names and other appropriate data on certified organic production and handling operations.

(8) *Continuation of Certification.* A few commenters recommended amending section 205.406 to include a safety net for producers who are certified by a certifying agent that does not become accredited by USDA. They stated that the rule must clearly state that a certified organic producer will have the full 18-month implementation period starting from the effective date of the final rule to get recertified if their certifying agent is not accredited. One of the commenters stated that because the NOP anticipates that the accreditation process will require 12 months, producers will, in effect, have 6 months to be certified by a new certifying agent should the producer's certifying agent not be accredited.

Certification under the NOP will become mandatory 18 months after the effective date of the final rule. Applications for accreditation will be processed on a first-come, first-served basis. Accreditations will be announced approximately 12 months after the effective date of the final rule for those qualified certifying agents who apply within the first 6 months following the effective date and for any other applicants that AMS determines eligible. Certifying agents will begin the process of certifying organic production and handling operations to the national standards upon receipt of their USDA accreditation. All production and handling operations certified by an accredited certifying agent will be considered certified to the national standards until the certified operation's anniversary date of certification. This phase-in period will only be available to those certified operations certified by a certifying agent that receives its accreditation within 18 months from the effective date of the final rule. We anticipate that certifying agents and production and handling operations will move as quickly as possible to begin operating under the national organic standards. Operations certified by a certifying agent, which fails to apply for or fails to meet the requirements for USDA accreditation under the NOP, must seek and receive certification by a USDA-accredited certifying agent before they can sell, label, or represent their products as organic, effective 18 months after the effective date of the final rule.

Subpart F—Accreditation of Certifying Agents

This subpart sets forth the requirements for a national program to accredit State and private entities as certifying agents to certify domestic or foreign organic production or handling operations. This subpart also provides that USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if: (1) USDA determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the foreign certifying agent meet the requirements of this part; or (2) the foreign governmental authority that accredited the certifying agent acted under an equivalency agreement negotiated between the United States Government and the foreign government.

This National Organic Program (NOP) accreditation process will facilitate national and international acceptance of U.S. organically produced agricultural commodities. The accreditation requirements in these regulations will, upon announcement of the first group of accredited certifying agents, replace the voluntary fee-for-service organic assessment program, established by AMS under the Agricultural Marketing Act of 1946. That assessment program verifies that State and private organic certifying agents comply with the requirements prescribed under the International Organization for Standardization/International Electrotechnical Commission Guide 65, ''General Requirements for Bodies Operating Product Certification Systems'' (ISO Guide 65).[2] ISO Guide 65 provides the general requirements that a certifying agent would need to meet to be recognized as competent and reliable. That assessment program was originally established to enable organic certifying agents in the absence of a U.S. national organic program to comply with European Union (EU) requirements beginning on June 30, 1999. That assessment program verifies that State and private organic certifying agents are operating third-party certification systems in a consistent and reliable manner, thereby facilitating uninterrupted exports of U.S. organic agricultural commodities to the EU. ISO Guide 65 was used as a benchmark in developing the accreditation program described in this final rule. Certifying agents accredited under the NOP that maintain compliance with the Act and these regulations will meet or exceed the requirements of ISO Guide 65; therefore, the organic assessment program is no longer needed.

Participation in the NOP does not preclude the accredited certifying agent from conducting other business operations, including the certification of agricultural products, practices, and procedures to standards that do not make an organic claim. An accredited certifying agent may not, however, engage in any business operations or activities which would involve the agent in a violation of or in a conflict of interest under the NOP.

Description of Regulations

The Administrator will accredit qualified domestic and foreign applicants in the areas of crops, livestock, wild crops, or handling or any combination thereof to certify domestic or foreign production or handling operations as certified organic operations. Qualified applicants will be accredited for 5 years.

Application Process

Certifying agents will apply to the Administrator for accreditation to certify production or handling operations operating under the NOP. The certifying agent's application must include basic business information, must identify each area of operation for which accreditation is requested and the estimated number of each type of operation to be certified annually, and must include a list of each State or foreign country where it currently certifies production or handling operations and where it intends to certify such operations. Certifying agents must also submit personnel, administrative, conflict of interest, current certification, and other documents and information to demonstrate their expertise in organic production or handling techniques, their ability to comply with and implement the organic certification program, and their ability to comply with the requirements for accreditation. Certifying agents planning to certify production or handling operations within a State with an approved State organic program (SOP) must demonstrate their ability to comply with the requirements of the SOP.

The administrative information submitted by the applicant must include copies of its procedures for certifying operations, for ensuring compliance of its certified operations with the Act and regulations, for complying with recordkeeping requirements, and for making information available to the

[2] ISO/IEC Guide 65 is available for viewing at USDA–AMS, Transportation and Marketing Programs, Room 2945–South Building, 14th and Independence Ave., SW., Washington, DC, from 9:00 a.m. to 4:00 p.m., Monday through Friday (except official Federal holidays). A copy may be obtained from the American National Standards Institute, 11 West 42d Street, New York, NY 10036; Website: www.ansi.org; E-mail: ansionline@ansi.org; Telephone: 212–642–4900; Facsimile: 212–398–0023.

public about certified operations. The procedures for certifying operations encompass the processes used by the certifying agent to evaluate applicants, make certification decisions, issue certification certificates, and maintain the confidentiality of any business information submitted by the certified operation. The procedures for ensuring compliance of the certified operations will include the methods used to review and investigate certified operations, for sampling and residue testing, and to report violations.

The personnel information submitted with the application must demonstrate that the applicant uses a sufficient number of adequately trained personnel to comply with and implement the organic certification program. The certifying agent will also have to provide evidence that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned. They must also show that all persons who review applications for certification perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and that all parties responsibly connected to the certifying agent have revealed existing or potential conflicts of interest.

Applicants who currently certify production or handling operations must also submit a list of the production and handling operations currently certified by them. For each area in which the applicant requests accreditation, the applicant should furnish copies of inspection reports and certification evaluation documents for at least three operations. If the applicant underwent any other accrediting process in the year previous to the application, the applicant should also submit the results of the process.

Certifying agents are prohibited from giving advice or providing consultancy services to certification applicants or certified operations for overcoming identified barriers to certification. This requirement does not apply to voluntary education programs available to the general public and sponsored by the certifying agent.

The Administrator will provide oversight of the fees to ensure that the schedule of fees filed with the Administrator is applied uniformly and in a nondiscriminatory manner. The Administrator may inform a certifying agent that its fees appear to be unreasonable and require that the certifying agent justify the fees. The Administrator will investigate the level of fees charged by an accredited certifying agent upon receipt of a valid complaint or under compelling circumstances warranting such an investigation.

Statement of Agreement

Upon receipt of the certifying agent's application for accreditation, the Administrator will send a statement of agreement to the person responsible for the certifying agent's day-to-day operations for signature. The statement of agreement affirms that, if granted accreditation as a certifying agent under this subpart, the applicant will carry out the provisions of the Act and the regulations in this part. Accreditation will not be approved until this statement is signed and returned to the Administrator.

The statement of agreement will include the applicant's agreement to accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to section 205.500 and the applicant's agreement to refrain from making false or misleading claims about its accreditation status, the USDA accreditation program, or the nature or qualities of products labeled as organically produced. Further, the statement will include the applicant's agreement to pay and submit the fees charged by AMS and to comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary. Applicants are also required to affirm through this statement of agreement that they will: (1) conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services; and (2) have an annual program review conducted of their certification activities by their staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation.

A private entity certifying agent must additionally agree to hold the Secretary harmless for any failure on the agent's part to carry out the provisions of the Act and regulations. A private entity certifying agent's statement will also include an agreement to furnish reasonable security for the purpose of protecting the rights of operations certified by such certifying agent. Such security will be in an amount and according to such terms as the Administrator may by regulation prescribe. A private entity certifying agent must agree to transfer all records or copies of records concerning its certification activities to the Administrator if it dissolves or loses its accreditation. This requirement for the transfer of records does not apply to a merger, sale, or other transfer of ownership of a certifying agent. A private entity certifying agent must also agree to make such records available to any applicable SOP's governing State official.

Granting Accreditation

Upon receiving all the required information, including the statement of agreement, and the required fee, the Administrator will determine if the applicant meets the requirements for accreditation. The Administrator's determination will be based on a review of the information submitted and, if necessary, a review of the information obtained from a site evaluation. The Administrator will notify the applicant of the granting of accreditation in writing. The notice of accreditation will state the area(s) for which accreditation is given, the effective date of the accreditation, any terms or conditions for the correction of minor noncompliances, and, for a private-entity certifying agent, the amount and type of security that must be established.

Certifying agents who apply for accreditation and do not meet the requirements for accreditation will be provided with a notification of noncompliance which will describe each noncompliance, the facts on which the notification is based, and the date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible. If the applicant is successful in its rebuttal or provides acceptable evidence demonstrating correction of the noncompliances, the NOP Program Manager will send the applicant a written notification of noncompliance resolution and proceed with further processing of the application. If the applicant fails to correct the noncompliances, fails to report the corrections by the date specified in the notification of noncompliance, fails to file a rebuttal by the date specified in the notification of noncompliance, or is unsuccessful in its rebuttal, the Program

Manager will issue a written notification of accreditation denial to the applicant. An applicant who has received written notification of accreditation denial may apply for accreditation again at any time or file an appeal of the denial of accreditation with the Administrator by the date specified in the notification of accreditation denial.

Once accredited, a certifying agent may establish a seal, logo, or other identifying mark to be used by certified production and handling operations. However, the certifying agent may not require use of its seal, logo, or other identifying mark on any product sold, labeled, or represented as organically produced as a condition of certification. The certifying agent also may not require compliance with any production or handling practices other than those provided for in the Act and regulations as a condition for use of its identifying mark. However, certifying agents certifying production or handling operations within a State with more restrictive requirements, approved by the Administrator, shall require compliance with such requirements as a condition of use of their identifying mark by such operations.

Site Evaluations

One or more representatives of the Administrator will perform site evaluations for each certifying agent in order to examine the certifying agent's operations and to evaluate compliance with the Act and regulations. Site evaluations will include an on-site review of the certifying agent's certification procedures, decisions, facilities, administrative and management systems, and production or handling operations certified by the certifying agent. A site evaluation of an accreditation applicant will be conducted before or within a reasonable time after issuance of the applicant's notification of accreditation. Certifying agents will be billed for each site evaluation conducted in association with an initial accreditation, amendments to an accreditation, and renewals of accreditation. Certifying agents will not be billed by USDA for USDA-initiated site evaluations conducted to determine compliance with the Act and regulations.

As noted above, a certifying agent may be accredited prior to a site evaluation. If the Program Manager finds, following the site evaluation, that an accredited certifying agent is not in compliance with the Act or regulations, the Program Manager will issue the certifying agent a written notification of noncompliance. If the certifying agent fails to correct the noncompliances, report the corrections by the date specified in the notification of noncompliance, or file a rebuttal by the date specified in the notification of noncompliance, the Administrator will begin proceedings to suspend or revoke the accreditation. A certifying agent that has had its accreditation suspended may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its accreditation. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and regulations. A certifying agent whose accreditation is revoked will be ineligible for accreditation for a period of not less than 3 years following the date of such determination.

Peer Review Panels

The Administrator shall establish a peer review panel pursuant to the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2 *et seq.*). The peer review panel shall be composed of not fewer than three members who shall annually evaluate the NOP's adherence to the accreditation procedures in subpart F of these regulations and ISO/IEC Guide 61,[3] General requirements for assessment and accreditation of certification/registration bodies, and the NOP's accreditation decisions. This will be accomplished through the review of: (1) accreditation procedures, (2) document review and site evaluation reports, and (3) accreditation decision documents or documentation. The peer review panel shall report its finding, in writing, to the NOP Program Manager.

Continuing Accreditation

An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following reports and fees: (1) A complete and accurate update of its business information, including its fees, and information evidencing its expertise in organic production or handling and its ability to comply with these regulations; (2) information supporting any changes requested in the areas of accreditation; (3) a description of measures implemented in the previous year and any measures to be implemented in the coming year to satisfy any terms and conditions specified in the most recent notification of accreditation or notice of renewal of accreditation; (4) the results of the most recent performance evaluations and annual program review and a description of adjustments to the certifying agent's operation and procedures implemented or to be implemented in response to the performance evaluations and program review; and (5) the required AMS fees.

Certifying agents will keep the Administrator informed of their certification activities by providing the Administrator with a copy of: (1) Any notice of denial of certification, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation issued simultaneously with its issuance and (2) a list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year.

One or more site evaluations will occur during the 5-year period of accreditation to determine whether an accredited certifying agent is complying with the Act and regulations. USDA will establish an accredited certifying agent compliance monitoring program, which will involve no less than one randomly selected site evaluation of each certifying agent during its 5-year period of accreditation. Larger and more diverse operations, operations with clients marketing their products internationally, and operations with a history of problems should expect more frequent site evaluations by USDA. Operations with clients marketing their products internationally will be annually site evaluated to meet the ISO-Guide 61 requirement for periodic surveillance of accredited certifying agents. USDA may also conduct site evaluations during investigations of alleged or suspected violations of the Act or regulations and in followup to such investigations. Such investigations will generally be the result of complaints filed with the Administrator alleging violations by the certifying agent. Compliance site evaluations may be announced or unannounced at the discretion of the Administrator. Certifying agents will not be billed by USDA for USDA-initiated site evaluations conducted to determine compliance with the Act and regulations.

[3] ISO/IEC Guide 61 is available for viewing at USDA–AMS, Transportation and Marketing Programs, Room 2945–South Building, 14th and Independence Ave., SW., Washington, DC, from 9:00 a.m. to 4:00 p.m., Monday through Friday (except official Federal holidays). A copy may be obtained from the American National Standards Institute, 11 West 42d Street, New York, NY 10036; Website: www.ansi.org; E-mail: ansionline@ansi.org; Telephone: 212–642–4900; Facsimile: 212–398–0023.

An accredited certifying agent must provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and these regulations. The certifying agent must maintain strict confidentiality with respect to its clients and not disclose to third parties (with the exception of the Secretary or the applicable SOP's governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing these regulations except as authorized by regulation. A certifying agent must make the following information available to the public: (1) Certification certificates issued during the current and 3 preceding calender years; (2) a list of producers and handlers whose operations it has certified, including for each the name of the operation, type(s) of operation, products produced, and the effective date of the certification, during the current and 3 preceding calender years; and (3) the results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and 3 preceding calender years. A certifying agent may make other business information available to the public if permitted in writing by the producer or handler. This information will be made available to the public at the public's expense.

An accredited certifying agent must maintain records according to the following schedule: (1) Records obtained from applicants for certification and certified operations must be maintained for not less than 5 years beyond their receipt; (2) records created by the certifying agent regarding applicants for certification and certified operations must be maintained for not less than 10 years beyond their creation; and (3) records created or received by the certifying agent pursuant to the accreditation requirements, excluding any records covered by the 10-year requirement, must be maintained for not less than 5 years beyond their creation or receipt. Examples of records obtained from applicants for certification and certified operations include organic production system plans, organic handling system plans, application documents, and any documents submitted to the certifying agent by the applicant/certified operation. Examples of records created by the certifying agent regarding applicants for certification and certified operations include certification certificates, notices of denial of certification, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, notification of suspension or revocation, correspondence with applicants and certified operations, on-site inspection reports, documents concerning residue testing, and internal working papers and memorandums concerning applicants and certified operations. Examples of records created or received by the certifying agent pursuant to the accreditation requirements include operations manuals; policies and procedures documents (personnel, administrative); training records; annual performance evaluations and supporting documents; conflict of interest disclosure reports and supporting documents; annual program review working papers, memorandums, letters, and reports; fee schedules; annual reports of operations granted certification; application materials submitted to the NOP; correspondence received from and sent to USDA; and annual reports to the Administrator.

The certifying agent must make all records available for inspection and copying during normal business hours by authorized representatives of the Secretary and the applicable SOP's governing State official. In the event that the certifying agent dissolves or loses its accreditation, it must transfer to the Administrator and make available to any applicable SOP's governing State official all records or copies of records concerning its certification activities. This requirement for the transfer of records does not apply to a merger, sale, or other transfer of ownership of a certifying agent.

Certifying agents are also required to prevent conflicts of interest and to require the completion of an annual conflict of interest disclosure report by all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent. Coverage of the conflict of interest provisions extends to immediate family members of persons required to complete an annual conflict of interest disclosure report. A certifying agent may not certify a production or handling operation if the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the production or handling operation, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification. A certifying agent may certify a production or handling operation if any employee, inspector, contractor, or other personnel of the certifying agent has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification. However, such persons must be excluded from work, discussions, and decisions in all stages of the certification process and the monitoring of the entity in which they have or have held a commercial interest. The acceptance of payment, gifts, or favors of any kind, other than prescribed fees, from any business inspected is prohibited. However, a certifying agent that is a not-for-profit organization with an Internal Revenue Code tax exemption or, in the case of a foreign certifying agent, a comparable recognition of not-for-profit status from its government, may accept voluntary labor from certified operations. Certifying agents are also prohibited from giving advice or providing consultancy services to certification applicants or certified operations for overcoming identified barriers to certification. To further ensure against conflict of interest, the certifying agent must ensure that the decision to certify an operation is made by a person different from the person who conducted the on-site inspection.

The certifying agent must reconsider a certified operation's application for certification when the certifying agent determines, within 12 months of certifying the operation, that a person participating in the certification process and covered under section 205.501(c)(11)(ii) has or had a conflict of interest involving the applicant. If necessary, the certifying agent must perform a new on-site inspection. All costs associated with a reconsideration of an application, including onsite inspection costs, shall be borne by the certifying agent. When it is determined that, at the time of certification, a conflict of interest existed between the applicant and a person covered under section 205.501(c)(11)(i), the certifying agent must refer the certified operation to a different accredited certifying agent for recertification. The certifying agent must also reimburse the operation for the cost of the recertification.

No accredited certifying agent may exclude from participation in or deny the benefits of the NOP to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status. Accredited certifying agents must accept all production and handling

applications that fall within their areas of accreditation and certify all qualified applicants, to the extent of their administrative capacity to do so, without regard to size or membership in any association or group.

Renewal of Accreditation

To avoid a lapse in accreditation, certifying agents must apply for renewal of accreditation at least 6 months prior to the fifth anniversary of issuance of the notification of accreditation and each subsequent renewal of accreditation. The Administrator will send the certifying agent a notice of pending expiration of accreditation approximately 1 year prior to the scheduled date of expiration. The accreditation of certifying agents who make timely application for renewal of accreditation will not expire during the renewal process. The accreditation of certifying agents who fail to make timely application for renewal of accreditation will expire as scheduled unless renewed prior to the scheduled expiration date. Certifying agents with an expired accreditation must not perform certification activities under the Act and these regulations.

Following receipt of the certifying agent's annual report and fees and the results of a site evaluation, the Administrator will determine whether the certifying agent remains in compliance with the Act and regulations and should have its accreditation renewed. Upon a determination that the certifying agent is in compliance with the Act and regulations, the Administrator will issue a notice of renewal of accreditation. The notice of renewal will specify any terms and conditions that must be addressed by the certifying agent and the time within which those terms and conditions must be satisfied. Renewal of accreditation will be for 5 years. Upon a determination that the certifying agent is not in compliance with the Act and regulations, the Administrator will initiate proceedings to suspend or revoke the certifying agent's accreditation. Any certifying agent subject to a proceeding to suspend or revoke its accreditation may continue to perform certification activities pending resolution of the proceedings to suspend or revoke the accreditation.

Amending Accreditation

An accredited certifying agent may request amendment to its accreditation at any time. The application for amendment must be sent to the Administrator and must contain information applicable to the requested change in accreditation, a complete and accurate update of the certifying agent's application information and evidence of expertise and ability, and the applicable fees.

Accreditation—Changes Based on Comments

This subpart differs from the proposal in several respects as follows:

(1) *Advice and Consultancy Services.* We have amended section 205.501(a)(11)(iv) to clarify that certifying agents are to prevent conflicts of interest by not giving advice or providing consultancy services to applicants for certification and certified operations for overcoming identified barriers to certification. This amendment has been made in response to a commenter who stated that the provisions of section 205.501(a)(11)(iv), as proposed, seemed to preclude the providing of advice and educational workshops and training programs. It was not our intent to prevent certifying agents from sponsoring in-house publications, conferences, workshops, informational meetings, and field days for which participation is voluntary and open to the general public. The provisions as originally proposed and as amended are intended to prohibit certifying agents from telling applicants and certified operations how to overcome barriers to certification identified by the certifying agent. It would be a conflict of interest for a certifying agent to tell an operation how to comply inasmuch as the certifying agents impartiality and objectivity will be lost should the advice or consultancy prove ineffective in resolving the noncompliance. The provisions of section 205.501(a)(11)(iv) are consistent with ISO Guide 61.

To further clarify this issue, we have also amended section 205.501(a)(16) by adding ''for certification activities'' after the word, ''charges.''

(2) *Conflicts of Interest—Persons Covered.* We have amended section 205.501(a)(11)(v) to limit the completion of annual conflict of interest disclosure reports to all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent. A commenter recommended amending section 205.501(a)(11)(v) to have it apply to all persons with direct oversight of or participation in the certification program rather than all persons identified in section 205.504(a)(2). Section 205.504(a)(2) includes all personnel to be used in the certification operation, including administrative staff, certification inspectors, members of any certification review and evaluation committees, contractors, and all parties responsibly connected to the certifying agent. We have decided that completion of annual conflict of interest disclosure reports by persons not involved in the certification process or responsibly connected to the certifying agent is unnecessary. As amended, section 205.501(a)(11)(v) includes all persons with the opportunity to influence the outcome of a decision on whether to certify a specific production or handling operation. Completed conflict of interest disclosure reports will be used by certifying agents to identify persons with interests in applicants for certification and certified operations that may affect the impartiality of such persons.

(3) *Reporting Certifications Granted.* We have amended section 205.501(a)(15)(ii) (formerly section 205.501(a)(14)(ii)) by replacing ''a quarterly calendar basis'' with ''January 2 of each year.'' A commenter stated that the requirement that certifying agents report certifications that they have granted on a quarterly basis to the Administrator is burdensome. The commenter requested that section 205.501(a)(14)(ii) be amended to require a midyear or end-year reporting. Section 205.501(a)(15)(ii) now requires the certifying agent to submit a list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year. Certifying agents can fulfill this requirement by providing an up-to-date copy of the list of producers and handlers required to be made available to the public by section 205.504(b)(5)(ii).

(4) *Notification of Inspector.* We have added a new section 205.501(a)(18) requiring the certifying agent to provide the inspector, prior to each on-site inspection, with previous on-site inspection reports and to notify the inspector of the certifying agent's decision relative to granting or denying certification to the applicant site inspected by the inspector. Such notification must identify any requirements for the correction of minor noncompliances. We have made this addition because we agree with the commenter that such information should be provided to the inspector and because the requirements are consistent with ISO Guide 61.

(5) *Acceptance of Applications.* We have added a new section 205.501(a)(19) requiring the certifying agent to accept all production or handling applications

for certification that fall within the certifying agent's areas of accreditation and to certify all qualified applicants, to the extent of their administrative capacity to do so, without regard to size or membership in any association or group. We have made this addition because we agree with the many commenters who requested that certifying agents be required to certify all qualified applicants. We recognize, however, that there may be times when the certifying agent's workload or the size of its client base might make it necessary for the certifying agent to decline acceptance of an application for certification within its area of accreditation. This is why we have included the proviso, ''to the extent of their administrative capacity to do so.'' We have included ''without regard to size or membership in any association or group'' to address commenter concerns about discrimination in the providing of certification services. This addition is consistent with ISO Guide 61.

(6) *Ability to Comply with SOP.* We have added a new section 205.501(a)(20) requiring the certifying agent to demonstrate its ability to comply with an SOP, to certify organic production or handling operations within the State. This change, as pointed out by a State commenter, is necessary to clarify that a certifying agent must be able to comply with an SOP to certify production or handling operations within that State.

(7) *Performance Evaluation.* We have amended section 205.501(a)(6) by replacing ''appraisal'' with ''evaluation'' and expanding the coverage from inspectors to persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions. Corresponding amendments have also been made to section 205.510(a)(4). Further, we have amended section 205.501(a)(6) to clarify that the deficiencies to be corrected are deficiencies in certification services. We changed ''appraisal'' to ''evaluation'' at the request of a State commenter who pointed out that State inspectors generally perform other duties in addition to the inspection of organic production or handling operations. We concur that this change will help differentiate between the State's employee performance appraisal for all duties as a State employee and the evaluation of certification services provided under the NOP. Expanding the coverage from inspectors to all persons involved in the certification process makes the regulation consistent with ISO Guide 61. Sections 205.505(a)(3) and 205.510(a)(4) have been amended to make their language consistent with the changes to section 205.501(a)(6).

(8) *Annual Program Evaluation.* We have amended section 205.501(a)(7) by replacing ''evaluation'' with ''review'' and by replacing ''evaluations'' with ''reviews.'' A commenter suggested amending section 205.501(a)(7) by replacing the requirement of an annual program evaluation with an annual review of program activities. We agree that ''review'' is a more appropriate term than ''evaluate'' since to review is to examine, report, and correct while evaluate is more in the nature of assessing value. We have not, however, accepted that portion of the commenter's suggestion which would have removed the reference to the review being conducted by the certifying agent's staff, an outside auditor, or a consultant who has the expertise to conduct such reviews. We have not accepted this suggestion because the comment would have limited the review to being conducted by the certifying agent with no requirement that the certifying agent be qualified to conduct the review. Another commenter wanted to change the requirement to an annual assessment of the quality of the inspection system. We have not accepted this suggestion because it can be interpreted as narrowing the scope of the review from the full certification program to just the inspection component of the certification program. This commenter would also have limited the review to being conducted by the certifying agent with no requirement that the certifying agent be qualified to conduct the review. We believe that narrowing the scope of the review would be inconsistent with ISO Guide 65. It is also inconsistent with our intent that the entire certification program be reviewed annually. We also received a comment stating that it is a violation of ISO Guide 65 to have staff perform an internal review. We disagree with this commenter. ISO Guide 65 provides that the certification body shall conduct periodic internal audits covering all procedures in a planned and systematic manner. Sections 205.505(a)(4) and 205.510(a)(4) have been amended to make their language consistent with the changes to section 205.501(a)(7).

(9) *Certification Decision.* We have added a new section 205.501(a)(11)(vi) that requires the certifying agent to ensure that the decision to certify an operation is made by a person different from the person who carried out the on-site inspection. Commenters requested that this provision be added to the requirement that certifying agents prevent conflicts of interest. We concur with the request because it clearly separates the act of inspecting an organic operation from the act of granting certification. This addition is also consistent with ISO Guide 65, section 4.2(f), which requires that the certification body ensure that each decision on certification is taken by a person different from those who carried out the evaluation.

(10) *Determination of Conflict of Interest.* We have added a new section 205.501(a)(12) addressing situations where a conflict of interest present at the time of certification is identified after certification. Several commenters requested the addition of a provision that, if a conflict of interest is identified within 12 months of certification, the certifying agent must reconsider the application and may reinspect the operation if necessary. We agree with the commenters that the issue of conflicts of interest present at the time of certification but identified after certification need to be addressed in the regulations. Accordingly, we have provided that an entity accredited as a certifying agent must reconsider a certified operation's application for certification and, if necessary, perform a new on-site inspection when it is determined, within 12 months of certifying the operation, that any person participating in the certification process and covered under section 205.501(a)(11)(ii) has or had a conflict of interest involving the applicant. Because the certifying agent is responsible for preventing conflicts of interest, all costs associated with a reconsideration of application, including onsite inspection costs, must be borne by the certifying agent. Further, a certifying agent must refer a certified operation to a different accredited certifying agent for recertification when it is determined that any person covered under section 205.501(a)(11)(i) at the time of certification of the applicant had a conflict of interest involving the applicant. Because the certifying agent is responsible for preventing conflicts of interest, the certifying agent must reimburse the operation for the cost of the recertification. Sections 205.501(a)(12) through 205.501(a)(17) have been redesignated as sections 205.501(a)(13) through 205.501(a)(18), respectively.

(11) *Financial Security.* We published an advanced notice of proposed rulemaking and request for comments regarding financial security in the

August 9, 2000, issue of the **Federal Register**. We issued a news release announcing the **Federal Register** publication on August 9, 2000. Numerous commenters expressed concern about reasonable security relative to its amount and impact on small certifying agents. A few commenters requested a definition for reasonable security. Others stated that the formula for determining the amount of security should be published in the **Federal Register**. The March 13, 2000, NOP proposed rule stated that the amount and terms of reasonable financial security would be the subject of additional rulemaking. The August 9, 2000, advanced notice of proposed rulemaking solicited comments on all aspects of reasonable security and protection of the rights of program participants. We requested comments from any interested parties, including producers and handlers of organic agricultural products, certifying agents, importers and exporters, the international community, and any other person or group. Six questions were provided to facilitate public comment on the advanced notice of proposed rulemaking. Comments addressing other relevant issues were also invited. The questions posed in the advanced notice of proposed rulemaking were:

(a) From what risks or events might a customer of a private certifying agent require reasonable security?

(b) What are the financial instrument(s) that could provide the reasonable security to protect customers from these events?

(c) What dollar amounts of security would give reasonable protection to a customer of a private certifying agent?

(d) What are the financial costs to private certifiers, especially small certifiers, of providing reasonable security?

(e) Do the risks or events provided in response to question #1 necessarily require financial compensation?

(f) Are there situations in which reasonable security is not needed?

Following analysis of the comments received, we will publish a proposed rule on reasonable security in the **Federal Register**. The public will again be invited to submit comments. The proposed rule will include the proposed regulation, an explanation of the decision-making process, an analysis of the costs and benefits, the effects on small businesses, and an estimate of the paperwork burden imposed by the regulation.

(12) *Use of Identifying Mark.* We have amended section 205.501(b)(2) to clarify that all certifying agents (private and State) certifying production or handling operations within a State with more restrictive requirements, approved by the Secretary, shall require compliance with such requirements as a condition of use of their identifying mark by such operations. Numerous commenters stated that they wanted USDA to permit higher production standards by private certifying agents. See also item 17 under Accreditation—Changes Requested But Not Made. This amendment is intended to further clarify our position that no certifying agent (State or private) may establish or require compliance with its own organic standards. It is an SOP, not a State certifying agent, that receives approval from the Secretary for more restrictive requirements. See also item 7 under Accreditation—Clarifications.

(13) *Transfer of Records.* To address the issues of a merger, sale, or other transfer of ownership, we have added the following to the end of section 205.501(c)(3); ''*Provided*, That, such transfer shall not apply to a merger, sale, or other transfer of ownership of a certifying agent.'' Commenters suggested amending section 205.501(c)(3) to provide for the transfer of records accumulated from the time of accreditation to the Administrator or his or her designee, another accredited certifying agent, or an SOP's governing State official in a State where such official exists. It was also stated that this section needs to take into account a certifying agent's decision to merge or transfer accounts to another certifying agent in the case of loss of accreditation. Under the NOP, should a certifying agent dissolve or lose its accreditation, its certified operations will be free to seek certification with the accredited certifying agent of their choice. Accordingly, it would be inappropriate to automatically transfer an operation's records to another certifying agent as requested by the commenters. However, in analyzing the comments, we realized that a provision was needed for a merger, sale, or other transfer of ownership of a certifying agent; thus, the amendment to section 205.501(c)(3). Section 205.505(b)(3) has been amended to make its language consistent with the changes to section 205.501(c)(3).

(14) *Fees for Information.* We have amended section 205.504(b)(5) by inserting ''including any fees to be assessed'' after the word, ''used.'' This change is made in response to the question of whether fees may be charged for making information available to the public. It is our intent that certifying agents may charge reasonable fees for document search time, duplication, and, when applicable, review costs. We anticipate that review costs will most likely be incurred when the information requested is located within documents which may contain confidential business information.

(15) *Information Available to the Public.* We have amended section 205.504(b)(5)(ii) by adding products produced to the information to be released to the public. This addition responds in an alternate way to commenters who wanted the information included on certificates of organic operation. That request was denied; see item 4, Changes Requested But Not Made, under subpart E, Certification. This addition is consistent with ISO Guide 61.

(16) *Equivalency of Certification Decisions and Statement of Agreement.* We have amended sections 205.501(a)(12) (redesignated as 205.501(a)(13)) and 205.505(a)(1) by deleting the words, ''USDA accredited'' and ''as equivalent to its own,'' and adding to the end thereof: ''accredited or accepted by USDA pursuant to section 205.500.'' We have made this amendment to clarify that the provision applies to certification decisions by domestic certifying agents as well as foreign certifying agents accredited or accepted by USDA pursuant to section 205.500.

There were many comments in support of section 205.501(a)(12) as written. However some did not agree that certifying agents should have to recognize another agent's decision as equivalent to their own. These commenters want to maintain the right and ability not to use their seal on a product that does not meet their standards. The most strongly voiced comment stated: ''delete section 205.501(a)(12) and section 205.505(a)(1). The requirements constitute a ''taking'' in violation of the Fifth Amendment and are unnecessary to accomplish the goal of establishing a consistent standard and facilitating trade.''

We do not concur with the commenters who want to change sections 205.501(a)(12) and 205.505(a)(1). We also do not agree with the comment that sections 205.501(a)(12) and 205.505(a)(1) constitute a taking in violation of the Fifth Amendment and are unnecessary to accomplish the goal of establishing a consistent standard and facilitating trade. We believe that, to accomplish the goal of establishing a consistent standard and to facilitate trade, it is vital that an accredited certifying agent accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to section 205.500. All domestic organic production and handling operations, unless exempted or excluded under

section 205.101, must be certified to these national standards and, when applicable, any State standards approved by the Secretary. All domestic certified operations must be certified by a certifying agent accredited by the Administrator. No USDA-accredited certifying agent, domestic or foreign, may establish or require compliance with its own organic standards. Certifying agents are not required to have an identifying mark for use under the NOP. However, if a certifying agent is going to use an identifying mark under the NOP, the use of such mark must be voluntary and available to all of the certifying agent's clients certified under the NOP. Accordingly, we have not changed the requirement that a certifying agent accept the certification decisions made by another USDA-accredited certifying agent. We have, however, as noted above, amended both sections to require that USDA-accredited certifying agents accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to section 205.500.

(17) *Granting Accreditation.* We have made editorial changes to section 205.506 consistent with the suggestion that we replace ''approval of accreditation'' with ''granting of accreditation.'' In the title to section 205.506, we have replaced ''Approval of'' with ''Granting.'' In section 205.506(a), we have replaced ''approved'' with ''granted,'' and in section 205.506(b), we have replaced ''approval'' with ''the granting.'' We have made these change because, under the NOP, we grant accreditation rather than approve accreditation.

(18) *Correction of Minor Noncompliances.* We have added a new section 205.506(b)(3) providing that the notification granting accreditation will state any terms and conditions for the correction of minor noncompliances. Commenters requested the addition of language to section 205.506(b) which would clarify that the Administrator may accredit with required corrective actions for minor noncompliances. In the proposed rule, we addressed accreditation subject to the correction of minor noncompliances at section 205.510(a)(3). We agree with commenters that, for the purposes of clarity, this issue should also be addressed in section 205.506 on the granting of accreditation. Accordingly, we have added new section 205.506(b)(3) as noted above. We have also retained the provisions of section 205.510(a)(3), which requires certifying agents to annually report on actions taken to satisfy any terms and conditions addressed in the most recent notification of accreditation or notice of renewal of accreditation. Section 205.506(b)(3) has been redesignated as section 205.506(b)(4).

(19) *Denial of Accreditation.* We have amended section 205.507 to include noncompliance and resolution provisions originally included by cross-reference to section 205.665(a). This cross-reference created confusion for commenters, regarding section 205.665's applicability to applicants for accreditation because the section does not specifically address applicants. Rather than specifically identifying applicants within section 205.665, we believe the issue is best clarified by addressing noncompliance and resolution within section 205.507. As amended, section 205.507 now states in paragraph (a) that the written notification of noncompliance must describe each noncompliance, the facts on which the notification is based, and the date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible. This rewrite of paragraph (a) also enabled us to eliminate paragraph (b) since its provisions are addressed in amended paragraph (a). The section also provides, at new paragraph (b), that when each noncompliance has been resolved, the Program Manager will send the applicant a written notification of noncompliance resolution and proceed with further processing of the application. We have also clarified the applicant's appeal rights by adding ''or appeal the denial of accreditation in accordance with section 205.681 by the date specified in the notification of accreditation denial'' to the end of paragraph (c).

(20) *Reinstatement of Accreditation.* We have amended section 205.507(d) by removing the requirement that a certifying agent that has had its accreditation suspended reapply for accreditation in accordance with section 205.502. In its place, we provide that the certifying agent may request reinstatement of its accreditation. Such request may be submitted at any time unless otherwise stated in the notification of suspension. Amended section 205.507(d) also provides that the certifying agent's request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. We have made this change because unlike revocation, suspension does not terminate a certifying agent's accreditation. Accordingly, requiring a new application for accreditation is unnecessary and burdensome on the certifying agent. This change is consistent with changes to sections 205.662(f) and 205.665(g)(1), which were made based on comments received on section 205.662(f).

(21) *Ineligible for accreditation.* We have amended section 205.507(d) by deleting ''private entity'' from the third sentence. The amended sentence provides that ''A certifying agent whose accreditation is revoked will be ineligible for accreditation for a period of not less than 3 years following the date of such determination.'' Several commenters recommended deletion of ''private entity'' so that private certifying agents would be regulated on an equivalent basis with State certifying agents. It is our intent to regulate private and State certifying agents on an equivalent basis. Accordingly, we made the recommended change.

(22) *Peer Review.* We have amended section 205.509. As amended, the section requires that the Administrator establish a peer review panel pursuant to FACA (5 U.S.C. App. 2 *et seq.*). The peer review panel will be composed of not less than 3 members who will annually evaluate the NOP's adherence to the accreditation procedures in subpart F of these regulations and ISO/IEC Guide 61, General requirements for assessment and accreditation of certification/registration bodies, and the NOP's accreditation decisions. This will be accomplished through the review of accreditation procedures, document review and site evaluation reports, and accreditation decision documents and documentation. The peer review panel will report its finding, in writing, to the NOP's Program Manager. We developed this approach to peer review as a means of addressing the suggestions of the commenters and the need for administration of an effective and timely accreditation program.

Many commenters wanted the opening language in the first sentence of section 205.509 changed from ''The Administrator may'' to the ''The Administrator shall'' establish a peer review panel to assist in evaluating applicants for accreditation, amendment to an accreditation, and renewal of accreditation as certifying agents. One of the most frequent comments, including a comment by the NOSB, was that peer reviewers should be compensated for their time and expenses. Many commenters believe also that the peer review process should be collaborative. Some commenters who wanted this change recognized that a collaborative process where confidential information was shared could run into problems

because FACA (P.L. 92–463, 5 U.S.C. App.) meetings are open to the public. They advised creating a FACA panel but restricting public access during discussion of confidential business information based on 5 U.S.C. Section 522b(c)(4) of the Government in the Sunshine Act.

As requested, amended section 205.509 requires the formation of a peer review panel. Also as requested, peer reviewers, who will serve as a FACA committee, will be reimbursed for their travel and per diem expenses. The reviewers will also work collaboratively. We have not, however, provided for collaborative review of each applicant for accreditation by the peer review panel because of the administrative burden that an outside collaborative review process would place on the NOP. Currently, there are 36 private and 13 State certifying agencies. It is, therefore, likely that USDA will receive approximately 50 applications for accreditation the first year of the program. Given the need to make accreditation decisions in a timely, organized fashion, it would be infeasible to convene a panel of peers for each applicant for accreditation prior to rendering a decision on accreditation. However, as noted above, we have provided that a peer review panel will annually evaluate the NOP's adherence to the accreditation procedures in subpart F of these regulations and ISO/IEC Guide 61, General requirements for assessment and accreditation of certification/registration bodies, and validate the NOP's accreditation decisions.

We have also amended current section 205.510(c)(3) by removing the reference to reports submitted by a peer review panel to make that section consistent with the rewrite of section 205.509.

(23) *Expiration of accreditation.* We have added a new section 205.510(c)(1) which provides that the Administrator shall send the accredited certifying agent a notice of pending expiration of accreditation approximately 1 year prior to the scheduled date of expiration. A commenter suggested USDA notification of certifying agents at least 1 year prior to the scheduled expiration of accreditation. We have made the suggested change because we believe notification about 1 year prior to expiration will facilitate the timely receipt of applications for renewal. We have redesignated sections 205.510(c)(1) and 205.510(c)(2) as 205.510(c)(2) and 205.510(c)(3), respectively.

(24) *Amendments to Accreditation.* We have added a new section 205.510(f) to provide that an amendment to an accreditation may be requested at any time. The application for amendment must be sent to the Administrator and must contain information applicable to the requested change in accreditation. The application for amendment must also contain a complete and accurate update of the information submitted in accordance with section 205.503, Applicant information; and section 205.504, Evidence of expertise and ability. The applicant must also submit the applicable fees required in section 205.640. We have added this new section because we agree with the commenter who expressed concern that the regulations were not clear regarding amendments to accreditation. This addition is consistent with section 205.510(a)(2) which allows certifying agents to request amendment of their accreditation as part of their annual report to the Administrator.

Accreditation—Changes Requested But Not Made

This subpart retains from the proposed rule, regulations on which we received comments as follows:

(1) *Accreditation by USDA.* A commenter stated that ISO/IEC Guide 61 specifies, but the proposed rule did not specify, the requirements for USDA to assess and accredit certifying agents. The commenter questioned USDA's acceptance internationally as a competent accreditation body. A few commenters requested that USDA provide certifying agents with assurance of international trade acceptance of the USDA's accreditation program prior to implementation of the final rule. We do not believe that it is necessary to include in these regulations detailed procedures by which USDA will operate its accreditation program. USDA has developed its accreditation and certification programs with the intent that they meet or exceed international guidelines. Every country will make its own decision regarding acceptance of this accreditation program. Accordingly, while we do not anticipate problems with acceptance of our accreditation program, we cannot provide assurance against problems as requested by the commenters.

(2) *Equivalency at the European Community (EC) Level.* A commenter requested confirmation that an equivalency agreement would be negotiated at the EC level since the EC legislation provides for the basic rules while accreditation of certifying agents is a task for each member state. Another commenter pointed out that because Switzerland has the same regulations as the EC, equivalency would have to be done in close coordination with the EC. The commenter went on to say that according to Swiss and European practice, not only the organic product, but also the bodies involved will be mutually accepted. This commenter also stated that, due to Swiss import provisions, brokers must be subject to a certain control. Equivalency will be negotiated between the United States and the foreign government authority seeking the equivalency agreement.

(3) *Period of Accreditation.* It was suggested that accreditation should be for a 4-year period with full reevaluation occurring once every 4 years and annual surveillance visits in the intervening years. We do not concur with changing the period of accreditation from 5 years to 4 years as suggested. The 5-year period that we have provided that accreditation is consistent with the Act, which provides that accreditation shall be for a period of not to exceed 5 years. The commenter claims that the international norm is for full reevaluations to take place once every 4 years with annual surveillance visits in the intervening years. ISO Guide 61, section 3.5.1, provides that the accreditation body shall have an established documented program, consistent with the accreditation granted, for carrying out periodic surveillance and reassessment at sufficiently close intervals to verify that its accredited body continues to comply with the accreditation requirements. We believe that accreditation for 5 years is a reasonable period of time. Further, we believe that a 5-year period of accreditation is consistent with ISO Guide 61 inasmuch as we require an annual evaluation of the certification program; annual review of persons associated with the certification process, including inspectors; annual reporting with a complete and accurate update of information required for accreditation; and one or more site evaluations during the period of accreditation in addition to the initial site evaluation for the period of accreditation. Accordingly, we have not made the recommended change.

(4) *Accreditation by Private-Sector Accreditation Bodies.* Numerous commenters wanted language added to section 205.500(c) that would allow private sector accreditation bodies to accredit foreign certifying agents. For example, several commenters suggested adding a provision reading as follows: ''The foreign certifying agent is accredited by a private accreditation body recognized by the USDA as defined by an equivalency agreement negotiated between the USDA and the accreditation body.'' Commenters also wanted us to amend section 205.502(a)

to recognize accreditation by private accreditation programs.

USDA is the accrediting body for all accreditations under the NOP. USDA will not recognize nongovernmental accrediting bodies. USDA will recognize foreign certifying agents accredited by a foreign government authority when USDA determines that the foreign government's standards meet the requirements of the NOP or when an equivalency agreement has been negotiated between the United States and a foreign government.

(5) *Requirements for Accreditation.* Some commenters requested more specificity in the requirements for accreditation. For example, one recommended that section 205.501(a)(1) should include the requirement that inspectors demonstrate completion of a specified training program or internship or ongoing education and/or licensing. Another commenter wanted baseline criteria for denying an application due to expertise. Still others wanted a definition for (1) ''experience and training pertaining to organic/sustainable agricultural methods and their implementation on farm or in processing facilities,'' (2) ''trained certifying agent personnel,'' and (3) ''reasonable time.'' Finally, one wanted recordkeeping and evaluative parameters. AMS does not believe that it is necessary to present the requirements for accreditation to the extent of detail requested by the commenters. The intent is to provide flexibility to the certifying agents such that they can tailor their policies and procedures to the nature and scope of their operation. The NOP is available to respond to questions and to assist certifying agents in complying with the requirements for accreditation.

(6) *Volunteer Board Members.* Some commenters suggested amending section 205.501(a)(5) to include a reference to committees and to expand ''sufficient expertise'' to ''sufficient balance of interests and expertise.'' The commenters proposed the amendment to create a firewall between those persons involved in decision making and the volunteer board members. However, the purpose of section 205.501(a)(5) is to ensure that the persons used by the certifying agent to assume inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned. Therefore, we have not made the suggested changes. Conflict of interest guidelines are found at section 205.501(a)(11).

(7) *Confidentiality.* A commenter stated that Texas law prevents the Texas Department of Agriculture from guaranteeing confidentiality to its clients. Accordingly, the commenter requested that section 205.501(a)(10) be amended by adding to the end thereof: ''or as required by State statutes.'' We have not made the suggested change because the Act requires that the certifying agent maintain strict confidentiality with respect to its clients under the NOP and not disclose any business-related information concerning such client obtained while implementing the Act. To be accredited under the NOP, certifying agents must fully comply with the requirements of the Act and these regulations. Further, no SOP will be approved which does not comply with the NOP.

(8) *Certifying Agent Fees.* Several commenters requested that the regulations prohibit royalty formulas (i.e., fees from every certified sale) for certifying agent fees. It is not our intent to regulate how a certifying agent sets its fees beyond their being reasonable and nondiscriminatory.

(9) *Conflicts of Interest.* We received numerous comments stating that section 205.501(a)(11)(i) was too restrictive and unnecessary due to the provisions of section 205.501(a)(11)(ii) to prevent conflicts of interest. Some argued that these conflict of interest provisions are beyond ISO requirements and place an undue burden on membership based certifying agents and the entities they serve. They requested a conflict of interest policy enabling membership-based certification organizations to continue operating. A commenter suggested that section 205.501(a)(11) be amended to require that a certifying agent's board members sign an affidavit listing potential conflicts of interest, identify issues where an organization decision might help them personally, and exclude themselves from decision-making that would assist them personally. This commenter proposed the amendment for the purpose of creating a firewall between those persons involved in certification decision-making and the volunteer board members.

We do not believe that the conflict of interest provisions are too restrictive. These provisions are very similar to conflict of interest provisions under other USDA programs involving public-private partnerships (e.g., grain inspection). The certifying agent and its responsibly connected parties, including volunteer board members, hold positions of influence over the certifying agent's employees and persons with whom the certifying agent contracts for such services as inspection, sampling, and residue testing. Therefore, we continue to believe that avoiding such conflicts of interest is necessary to maintain the integrity of the organic certification process.

(10) *Conflicts of Interest and Prohibition on Certification.* A commenter requested that we include an ''or'' between sections 205.501(a)(11)(i) and 205.501(a)(11)(ii). We have not made the recommended change because both sections must be complied with; they are not mutually exclusive. Section 205.501(a)(11)(i) prohibits the certification of an applicant when the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the applicant for certification, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification. When the certifying agent and its responsibly connected persons are free of any conflict of interest involving the applicant for certification, the applicant may be certified if qualified. However, section 205.501(a)(11)(ii) requires the certifying agent to exclude any person (employees and contractors who do not meet the definition of responsibly connected), including contractors, with conflicts of interest from work, discussions, and decisions in all stages of the certification process and the monitoring of certified production or handling operations for all entities in which such person has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification.

(11) *Gifts and Contributions.* Commenters recommended that section 205.501(a)(11)(iii) be amended to allow not-for-profit organizations to accept gifts and contributions from certified operations for those programs not directly related to the certifying agent's organic certification activities. They also wanted it clarified that not-for-profit organizations can accept voluntary labor from certified operations for those programs not directly related to the certifying agent's organic certification activities. We have not made the requested changes. First, the acceptance of gifts and contributions would constitute a conflict of interest and would be contrary to ISO Guide 61. Certifying agents must have the financial stability and resources to perform their certification duties without relying on gifts and contributions from those they serve.

Second, we have not added the requested provision on voluntary labor because section 205.501(a)(11)(iii) already addresses the acceptance of voluntary labor by not-for-profit organizations from certified operations.

(12) *Conflicts of Interest—Determination Period.* Commenters wanted to increase the conflict determination period from 12 months to 24 months. Some also wanted the period to extend for 2 years after, with the exception of those who have left the employ of the certifying agent or are no longer under contract with the certifying agent.

We disagree with the recommendations calling for a longer precertification conflict of interest prohibition period. We continue to believe that 12 months is a sufficient period to ensure that any previous commercial interest would not create a conflict of interest situation for two reasons. First, this time period is consistent with similar provisions governing conflicts of interest for government employees. Second, section 205.501(a)(11)(v) requires the completion of an annual conflict of interest disclosure report by all personnel designated to be used in the certification operation, including administrative staff, certification inspectors, members of any certification review and program evaluation committees, contractors, and all parties responsibly connected to the certification operation. This requirement will assist certifying agents in complying with the requirements to prevent conflicts of interest. We also continue to believe that a longer prohibition period would have the effect of severely curtailing most certifying agents' ability to comply with the Act's requirement that they employ persons with sufficient expertise to implement the applicable certification program. Accordingly, we have not made the recommended change.

The change recommended by the commenters who requested that the conflict of interest determination period extend for 2 years after certification is unnecessary. Certifying agents and their responsibly connected parties, employees, inspectors, contractors, and other personnel are prohibited from engaging in activities or associations at any time during their affiliation with the certifying agent which would result in a conflict of interest. While associated with the certifying agent, all employees, inspectors, contractors, and other personnel are expected to disclose to the certifying agent any offer of employment they have received and not immediately refused. They are also expected to disclose any employment they are seeking and any arrangement they have concerning future employment with an applicant for certification or a certified operation. The certifying agent would then have to exclude that person from work, discussions, and decisions in all stages of the certification or monitoring of the operation making the employment offer. If a certifying agent or a responsibly connected party of the certifying agent has received and not immediately refused an offer of employment, is seeking employment, or has an arrangement concerning future employment with an applicant for certification, the certifying agent may not accept or process the application. Further, certifying agents and responsibly connected parties may not seek employment or have an arrangement concerning future employment with an operation certified by the certifying agent while associated with that certifying agent. Certifying agents and responsibly connected parties must sever their association with the certifying agent when such person does not immediately refuse an offer of employment from a certified operation. Accordingly, we have decided not to include a postcertification prohibition period in this final rule.

(13) *False and Misleading Claims.* A commenter asked who will determine what is a misleading claim about the nature or qualities of products labeled as organically produced. This same commenter recommended amending section 205.501(a)(13) by removing the prohibition against making false or misleading claims about the nature or qualities of products labeled as organically produced.

We disagree with this recommendation. Claims regarding accreditation status, the USDA accreditation program for certifying agents, and the nature and quality of products labeled as organically produced all fall under the authority of the Act. Accordingly, USDA will determine what is a misleading claim. We believe that the requirements are needed to prevent the dissemination of inaccurate or misleading information to consumers about organically produced products. We further believe that the change suggested by the commenter would undermine the goal of a uniform NOP by allowing certifying agents to make claims that would state or imply that organic products produced by operations that they certify are superior to those of operations certified by other certifying agents. These requirements would not prohibit certifying agents from sharing factual information with consumers, farmers, processors, and other interested parties regarding verifiable attributes of organic food and organic production systems. Accordingly, we have not made the recommended change to what is now section 205.501(a)(14).

(14) *Certifying Agent Compliance With Terms and Conditions Deemed Necessary.* A commenter recommended that we remove section 205.501(a)(17). This section requires that certifying agents comply with and implement other terms and conditions deemed necessary by the Secretary. This requirement is consistent with section 6515(d)(2) of the Act, which requires a certifying agent to enter into an agreement with the Secretary under which such agent shall agree to such other terms and conditions as the Secretary determines appropriate. Accordingly, we have not accepted the commenter's recommendation. This requirement is located at current section 205.501(a)(21).

(15) *Limitations on the Use of Certifying Agent's Marks.* Numerous commenters stated that they wanted USDA to permit higher production standards by private certifying agents. A common argument for allowing higher standards was that practitioners must be allowed to ''raise the bar'' through superior ecological on-farm practices or pursuit of other social and ecological goals. Some commenters recommended that the language in section 205.501(b)(2) be replaced with provisions that would allow certifying agents to issue licensing agreements with contract specifications that clearly establish conditions for use of the certifying agent's identifying mark.

We believe the positions advocated by the commenters are inconsistent with section 6501(2) of the Act, which provides that a stated purpose of the Act is to assure consumers that organically produced products meet a consistent national standard. We believe that, to accomplish the goal of establishing a consistent standard and to facilitate trade, it is vital that an accredited certifying agent accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to section 205.500. All organic production and handling operations, unless exempted or excluded under section 205.101 or not regulated under the NOP (i.e., a producer of dog food), must be certified to these national standards and, when applicable, any State standards approved by the Secretary. All certified operations must be certified by a certifying agent accredited by the Administrator. No accredited certifying agent may establish or require compliance with its

own organic standards. Accredited certifying agents may establish other standards outside of the NOP. They may not, however, refer to them as organic standards nor require that applicants for certification under the NOP or operations certified under the NOP comply with such standards as a requirement for certification under the NOP. Use of the certifying agent's identifying mark must be voluntary and available to all of its clients certified under the NOP. However, a certifying agent may withdraw a certified operation's authority to use its identifying mark during a compliance process. The certifying agent, however, accepts full liability for any such action.

The national standards implemented by this final rule can be amended as needed to establish more restrictive national standards. Anyone may request that a provision of these regulations be amended by submitting a request to the NOP Program Manager or the Chairperson of the NOSB. Requests for amendments submitted to the NOP Program Manager will be forwarded to the NOSB for its consideration. The NOSB will consider the requested amendments and make its recommendations to the Administrator. When appropriate, the NOP will conduct rulemaking on the recommended amendment. Such rulemaking will include an opportunity for public comment.

(16) *Evidence of Expertise and Ability.* A commenter stated that section 205.504, which addresses the documentation necessary to establish evidence of expertise and abilities, requires too much paperwork. We believe the amount of paperwork is appropriate for the task at hand, verifying a certifying agent's expertise in and eligibility for accreditation to certify organic production and handling operations to the NOP. We further believe that the level of paperwork is necessary to meet international guidelines for determining whether an applicant is qualified for accreditation as a certifying agent.

(17) *Procedures for Making Information Available to the Public.* Comments on section 205.504(b)(5) were mixed. Some commenters felt that the proposal fell short of the OFPA requirement to ''Provide for public access to certification documents and lab analysis.'' Others thought that too much confidential information would be released.

The Act requires public access, at section 2107(a)(9), to certification documents and laboratory analyses pertaining to certification. Accordingly, we disagree with those commenters who requested that such documents not be released to the public. We also disagree with the commenters who contend that the requirement for public disclosure falls short of what is required by the Act. Section 205.504(b)(5) meets the requirements of the Act by requiring the release of those documents cited in section 2107(a)(9) of the Act. The section also authorizes the release of other business information as authorized in writing by the producer or handler.

(18) *Accreditation Prior to Site Evaluation.* Numerous commenters recommended that we require site visits prior to accreditation. Some commenters cited ISO Guide 61, section 2.3.1, in their arguments for site visits prior to accreditation. ISO Guide 61, section 2.3.1., provides that the decision on whether to accredit a body shall be made on the basis of the information gathered during the accreditation process and any other relevant information. Section 3.3.2 of ISO Guide 61 provides that the accreditation body shall witness fully the on-site activities of one or more assessments or audits conducted by an applicant body before an initial accreditation is granted.

We do not concur with the commenters. These regulations provide for assessment of the applicant's qualifications and capabilities through a rigorous review of the application and supporting documentation. Following this review, an initial site evaluation shall be conducted before or within a reasonable period of time after issuance of the applicant's ''notification of accreditation.'' In cases where the document review raises concerns regarding the applicant's qualifications and capabilities and the Administrator deems it necessary, a preapproval site evaluation will be conducted. We have further provided that a site evaluation shall be conducted after application for renewal of accreditation but prior to renewal of accreditation.

Our purpose in allowing for initial accreditation prior to a site evaluation is to facilitate implementation of the NOP and to provide a means for newly established certifying agents to obtain a client base to demonstrate that they can meet the requirements of the NOP regulations. We believe this is consistent with the intent of ISO Guide 61, section 2.3.1. and fits within its ''and any other relevant information'' provision. Accordingly, we restate our position that accreditation approval without a site evaluation is appropriate, necessary in the case of established certifying agents that may need to make adjustments in their operations to comply with the NOP regulations, and necessary in the case of newly established certifying agents who will have to obtain a client base to demonstrate beyond the paperwork that they can meet the requirements of the NOP regulations.

(19) *Ineligibility After Revocation of Accreditation.* Section 205.507(d) provides that a certifying agent whose accreditation is revoked will be ineligible for accreditation for a period of not less than 3 years following the date of such determination. A commenter stated that the 3-year period of ineligibility is overly long and effectively puts the certifying agent out of business. The commenter suggested that a 6- to 12-month period might be reasonable. We have not accepted the suggested 6- to 12-month ineligibility period because the Act requires a period of ineligibility of not less than 3 years following revocation of accreditation.

(20) *Qualifications of the Site Evaluator.* A commenter recommended amending section 205.508(a) to indicate the required qualifications of the site evaluator. We have not accepted the recommendation. We do not believe that it is necessary to specify the required qualifications of site evaluators in these regulations. All USDA employees who will perform site evaluations under the NOP are quality systems auditors trained in accordance with internationally recognized protocols.

(21) *Complaint Process.* A commenter recommended that section 205.510 include a complaint process for complaints by certified operations regarding the performance of a certifying agent or inspector. The commenter also recommended that section 205.510 include a complaint process for the public should they feel that a certifying agent is not in compliance.

We do not believe that it is necessary to include a complaint process in the regulations. All interested parties are free to file a complaint with an accredited certifying agent, SOP's governing State official, or the Administrator at any time. We will provide guidance to accredited certifying agents and SOP's governing State officials regarding the type of information to gather when receiving a complaint. SOP's governing State officials will include in their request for approval of their SOP information on their collection of complaint information. Certifying agents will include details regarding the collection of complaint information and the investigation of complaints involving certified operations in their procedures for reviewing and investigating certified operation compliance (section

205.504(b)(2)). This will include maintaining records of complaints and remedial actions relative to certification as well as documentation of followup actions. Further, certifying agents will include details regarding the collection of complaint information and the investigation of complaints involving inspectors and other personnel employed by or contracted by the certifying agents in their policies and procedures for training, evaluating, and supervising personnel (section 205.504(a)(1)).

(22) *Recordkeeping by Certifying Agents.* A commenter stated that the 10-year recordkeeping requirement of section 205.510(b)(2) for records created by the certifying agent regarding applicants for certification and certified operations is excessive. The commenter recommended a 5-year retention period. We have not accepted the recommended 5-year records retention period for records created by the certifying agent regarding applicants for certification and certified operations because the Act requires the retention of such records for 10 years.

(23) *Reaccreditation.* A commenter recommended that section 205.510(c)(1) be amended to require reaccreditation every 3 years. We have provided that accreditation will be for a period of 5 years. This is consistent with the Act which provides that accreditation shall be for a period of not to exceed 5 years. The commenter believes that a 5-year period is not consistent with ISO Guide 61, section 3.5.1, which provides that the accreditation body shall have an established documented program, consistent with the accreditation granted, for carrying out periodic surveillance and reassessment at sufficiently close intervals to verify that its accredited body continues to comply with the accreditation requirements. We believe that accreditation for 5 years is a reasonable period of time. Further, we believe that a 5-year period of accreditation is consistent with ISO Guide 61 inasmuch as we require an annual evaluation of the certification program; annual review of persons associated with the certification process, including inspectors; annual reporting with a complete and accurate update of information required for accreditation; and one or more site evaluations during the period of accreditation in addition to the initial site evaluation for the period of accreditation. Accordingly, we have not made the recommended change. This requirement is located at current section 205.510(c)(2).

(24) *Notice of Renewal of Accreditation.* A commenter recommended that section 205.510(d) be amended to include a timeframe within which the Administrator must notify an applicant of its renewal of accreditation. We believe that a mandated timeframe for notifying the applicant of renewal of accreditation is inappropriate. We plan to process all applications for renewal of accreditation in the order in which they are received, to confirm the receipt of each application, and to establish a dialog with the applicant upon confirmation of receipt of an application for renewal of accreditation. The length of the renewal process will depend in large part on the nature of the operation seeking renewal of accreditation. To minimize the chances that an accreditation will expire during the renewal process, we have: (1) provided that the Administrator shall send the accredited certifying agent a notice of pending expiration of accreditation approximately 1 year before the date of expiration of the certifying agent's accreditation, (2) required that an application for renewal of accreditation must be received at least 6 months prior to expiration of the certifying agent's accreditation, and (3) provided that the accreditation of a certifying agent who makes timely application for renewal of accreditation will not expire during the renewal process. Accordingly, we have not made the recommended amendment.

Accreditation—Clarifications

Clarification is given on the following issues raised by commenters as follows:

(1) *Accreditation of Foreign Certifying Agents.* A commenter suggested that section 205.500 be amended to provide that if there is a government system operating in a foreign country then the government is the appropriate pathway for that country to apply for accreditation.

USDA will accept an application for accreditation to perform certification activities under the NOP from any private entity or governmental entity certifying agent and accredit such applicant upon proof of qualification for accreditation. USDA will provide for USDA accreditation of certifying agents and acceptance of a foreign government's accreditation of certifying agent within the same country. This maximizes opportunity for certifying agents without the potential for confusion and overlap in documentation. Further, we believe these requirements facilitate world trade.

(2) *State Approval of Product From Foreign Countries.* A commenter stated that any product making claims of organic agricultural ingredients to be sold in California shall fall under the jurisdiction of the California Organic Program for enforcement, inspection, and certification direction. The commenter further stated that, should any foreign certifying agents be accepted, they too shall be subject to the sovereign rights of the State of California to protect and enforce the laws of the State of California and to protect agricultural claims in this State.

Any organic program administered by a State will have to be approved by the Secretary. Approval of an SOP will be contingent upon the State's agreeing to accept the certification decisions made by certifying agents accredited or accepted by USDA pursuant to section 205.500.

(3) *Equivalency.* A commenter stated that USDA should declare in section 205.500 that there are no alternative methods of production that meet the Congressional purpose ''to assure consumers that organically produced products meet a consistent standard.'' The commenter went on to state that, if USDA proceeds with equivalency then the regulations should be amended to provide for: (1) No importing until final determination, (2) no final determination until Federal Register publication and public comment, (3) audit of foreign agency and production sites, and (4) revocation of accreditation for violations. The commenter also recommended that foreign certifying agents be reviewed with the same frequency as State certifying agents.

We disagree that there are no alternative methods of production that assure consumers that organically produced products meet a consistent standard. Accordingly, we will negotiate equivalency agreements with foreign governments. A final equivalency agreement will be required before affected product may be imported into the United States and sold, labeled, or represented as organic. Equivalency agreements will be announced to the public through a notice in the **Federal Register** and a news release. Site evaluations are a possibility. Foreign certifying agents that receive USDA accreditation, rather than recognition through their government, will have to fully comply with the NOP and will be treated the same as domestic accredited certifying agents.

(4) *Evaluation of Equivalency.* Commenters asked how equivalency would be evaluated and recommended basing equivalency, not on a check of formalities, but on the finding of substantive equivalence and equivalent effectiveness of certifying systems.

The negotiation of an equivalency agreement will involve meetings between representatives of the foreign

government seeking equivalency and representatives of USDA's Agricultural Marketing Service and Foreign Agricultural Service. Support will be provided by the Office of the U.S. Trade Representative. The process will also include the review of documents and possibly one or more site evaluations. Equivalency agreements will be announced to the public through a notice in the **Federal Register** and a news release.

(5) *Treatment of Certifying Agents Operating in More Than One Country.* A few commenters requested that we amend section 205.500(c) by adding a provision to clarify the issue of how the international activities of foreign or domestic certifying agents will be treated when they operate in more than one country.

We believe that the requested provision is unnecessary. Certifying agents, domestic and foreign, accredited under the NOP will be expected to comply fully with the requirements of the NOP regardless of where they operate. The only exception would be when they operate in a country in which the Secretary has negotiated an equivalency agreement.

(6) *Accreditation of Foreign Certifying Agents.* A commenter requested that we amend section 205.500(c) to exempt foreign applicants from having to be accredited certifying agents in USDA's program if the exporting country's national organic program meets international standards; e.g, Codex guidelines.

We have provided for USDA accreditation of qualified foreign certifying agents upon application. We have also provided that USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if it determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the foreign certifying agent meet the requirements of this part. We have further provided that USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if the foreign government authority that accredited the foreign certifying agent acted under an equivalency agreement negotiated between the United States and the foreign government. These recognitions of foreign government programs, however, do not extend to international standards such as Codex guidelines. In either case, we are recognizing the ability of a foreign government's program to meet U.S. standards, not some other international standard.

(7) *States with an Organic Statute.* A commenter stated that a State with an organic statute or regulations that does not certify organic producers or organic handlers should not have to be accredited.

The NOP requires the Secretary's approval of SOP's whether or not the State has a State certifying agent. A State may have an SOP but not have a State certifying agent. In this case the SOP must be approved by the Secretary. A State may have a State certifying agent but no SOP. In this case, the State certifying agent must apply for and receive accreditation to certify organic production or handling operations. Finally, a State may have an SOP and a State certifying agent. In this case, the SOP must be approved by the Secretary, and the State certifying agent must apply for and receive accreditation to certify organic production or handling operations.

(8) *Nondiscriminatory Services.* A commenter wanted the addition of a provision in section 205.501(a) requiring certifying agents to provide nondiscriminatory services. We have not included the suggested addition in this final rule because the provision already exists in section 205.501(d).

(9) *Release of Information.* A few commenters requested that we amend section 205.501(a)(10) to include a general exclusion allowing the release of any information with the client's permission. We have not included the suggested addition in this final rule because section 205.504(b)(5)(iv) already addresses the allowed release of other business information as permitted in writing by the producer or handler.

(10) *Use of the Term, ''Certified Organic.''* In commenting on section 205.501(b)(1), a commenter stated that if the term, ''certified organic,'' is included on a label, it must state by whom, according to Maine State law. We do not believe that the requirements of section 205.501(b)(1) would preclude a certified operation from complying with a State law requiring identification of the certifying agent on a product sold, labeled, or represented as ''certified organic.'' Further, these regulations do not require a certified operation to use the word, ''certified,'' on its label.

(11) *Holding the Secretary Harmless.* In commenting on the requirements of section 205.501(c)(1), a commenter stated that certifying agents are responsible for representing USDA but seem to have no recourse. Another commenter asked, what happens if a certifying agent is found in violation of the Act but the violation was due to information or direction that came from USDA?

Under the NOP, accredited certifying agents are required to comply with and carry out the requirements of the Act and these regulations. If they fail to do so, they are responsible for their actions or failures to act. This would not be true if the action or failure to act was at the direction of the Secretary.

(12) *Self-evaluation of Ability to Comply.* A commenter requested that section 205.504 be amended to provide clarity on the baseline requirements that would allow a certifying agent to conduct a self-evaluation to determine its ability to comply. The commenter stated that there should be some type of baseline acceptance of expertise and ability. The commenter wants details regarding the ''training'' or ''experience'' requirements necessary to qualify for accreditation. This commenter also stated that criteria for inspector and reviewer training should be added and enlarged.

We do not believe that it is necessary to present the requirements for accreditation to the extent of detail requested by the commenter. The intent is to provide flexibility to the certifying agents such that they can tailor their policies and procedures to the nature and scope of their operation. The NOP is available to respond to questions and to assist certifying agents in complying with the requirements for accreditation.

(13) *Evidence of Expertise and Ability.* Commenters stated that important elements of ISO Guide 65 are missing from section 205.504. They cite the maintenance of a complaints register and a register of precedents and provisions for subcontracting and a documents control policy or a document register.

Certifying agents grant certification, deny certification, and take enforcement action against a certified operation's certification. Certifying agents are required to maintain records applicable to all such actions and to report such actions to the Administrator. Certifying agents may contract with qualified individuals for the performance of services such as inspection, sampling, and residue testing. Certifying agents are required to submit personnel information (employed and contracted) and administrative policies and procedures to the Administrator. All such documents must be updated annually. The regulations also require the maintenance of records according to specified retention periods. All of these factors will be considered in granting or denying accreditation. We believe these requirements meet or exceed the ISO Guide 65 guidelines.

(14) *Personnel Evidence of Expertise.* A commenter inquired about the

frequency at which the personnel information, required by section 205.504(a) and used to establish evidence of expertise and ability, is to be updated. Section 205.510 requires that the certifying agent annually submit a complete and accurate update of the information required in section 205.504.

(15) *Responsibly Connected.* A commenter stated that the term, ''responsibly connected,'' as used in section 205.504(a)(2) is a broad sweep. The commenter believes the term would include everyone they do business with.

Section 205.504(a)(2) requires the certifying agent to provide the name and position description of all personnel to be used in the certification operation. The section assists the certifying agent in meeting the requirement by identifying categories of persons covered by the requirement including persons responsibly connected to the certifying agent. Responsibly connected does not include everyone that the certifying agent does business with. Responsibly connected is defined in the Definitions subpart of this final rule as ''any person who is a partner, officer, director, holder, manager, or owner of 10 percent or more of the voting stock of an applicant or a recipient of certification or accreditation.'' This definition has not changed.

(16) *Independent Third-Party Inspectors.* A commenter recommended amending section 205.504(a)(3)(I) to provide for the use of independent third-party inspectors. We believe that this recommended amendment is unnecessary since nothing in these regulations precludes a certifying agent from contracting with independent third parties for inspection services.

(17) *Response to Accreditation Applicant.* A commenter requested that section 205.506(a)(3) be amended to provide a timeframe within which the Administrator has to respond to the accreditation application. While section 205.506(a)(3) identifies the information to be reviewed by the Administrator prior to the granting of accreditation, we assume the commenter is seeking a specific time limit by which the Administrator will acknowledge receipt of an application for accreditation. In the alternative, the commenter may have been seeking a specific time limit by which the Administrator must grant or deny accreditation. We believe that a regulation-mandated timeframe for notifying the applicant of receipt of an application or for granting or denying accreditation is unnecessary. We plan to process all applications in the order in which they are received, to confirm the receipt of each application upon receipt, and to establish a dialog with the applicant upon confirmation of receipt of an application for accreditation. We will work with each applicant to complete the accreditation process as expeditiously as possible. A firm timeframe, however, cannot be set for granting or denying accreditation due to the anticipated uniqueness of each applicant and its application for accreditation.

(18) *Duration of Accreditation and Certification.* A commenter asked, ''How can certification be essentially in perpetuity and accreditation have a time restraint?'' The commenter's question does not indicate a preference for certification or accreditation longevity. The commenter correctly points out that certification and accreditation, both of which must be updated annually, are granted for different time periods. The Act limits the period of accreditation to 5 years but does not establish a limit to the period of certification. We believe the requirement that the certified operation submit an annual update of its organic plan negates the need for a certification expiration date.

(19) *Denial of Accreditation.* In commenting on section 205.507, a commenter stated that the regulations need to address what happens to a certifying agent's clients when the certifying agent fails to qualify for accreditation on its first attempt.

Section 205.507(c) provides that an applicant who has received written notification of accreditation denial may apply for accreditation again at any time in accordance with section 205.502. Upon implementation of the certification requirements of the NOP, production and handling operations planning to sell, label, or represent their products as organic must be certified by a USDA-accredited certifying agent before selling, labeling, or representing their products as organic. If a producer's or handler's choice of certifying agents does not receive USDA accreditation, the producer or handler must seek and receive certification under the NOP from a USDA-accredited certifying agent before selling, labeling, or representing their products as organic. Producers and handlers not so certified may not sell, label, or represent their products as organic. Any producer or handler who violates this requirement will be subject to prosecution under section 2120 of the Act.

(20) *Loss of Accreditation After Initial Site Visit.* Commenting on section 205.508(b), a commenter stated the belief that accreditation before a site visit may cause problems if the certifying agent does not meet the requirements and, subsequently, loses its accreditation. We believe the problems will be no greater than will occur at any other time when it becomes necessary to revoke a certifying agent's accreditation, including when it becomes necessary to initiate proceedings to suspend or revoke the certification of one or more of the certifying agent's certified operations. However, just because revocation of a certifying agent's accreditation may be justified, it may not be necessary to suspend or revoke the certification of one or more of its clients. An operation certified by a certifying agent that has lost its accreditation must make application with a new certifying agent if it is going to continue to sell, label, or represent its products as organic.

(21) *Prohibition on Certification After Expiration of Accreditation.* A commenter stated that, ''USDA should allow certifying agents to apply the same provisions to expiration of certification of a certified operation.'' The provision referenced by the commenter is the section 205.510(c)(1) (current section 205.510(c)(2)) requirement that certifying agents with an expired accreditation must not perform certification activities under the Act and these regulations. We have not accepted the commenter's request that the same prohibition be applied to production and handling operations with an expired certification because certification does not expire.

(22) *Expiration of Accreditation.* Many commenters requested that we amend section 205.510(c)(1) to require annual reports and ''minivisits.'' The commenters cited ISO Guide 61, section 3.5.1. We do not believe that annual ''minivisits'' are necessary to meet the requirements of ISO Guide 61 or to assure compliance with the NOP. One or more site evaluations will be conducted during the period of accreditation. The certifying agent's annual report will be used as a determining factor in whether to conduct a site evaluation. A request for amendment to a certifying agent's area of accreditation will also result in a site evaluation. This requirement is located at current section 205.510(c)(2).

(23) *Update and Review of Inspector Lists.* In commenting on section 205.510(c)(1) (current section 205.510(c)(2)) several commenters stated that updating and review of inspector lists must occur more frequently than every 5 years. They cited ISO Guide 61, section 3.5.1.

Section 205.510(a)(1) requires that the certifying agent annually update the information required in section 205.504. This includes the inspector information required by paragraphs 205.504(a)(2) and 205.504(a)(3)(i).

Subpart G—Administrative

The National List of Allowed and Prohibited Substances

Description of Regulations

General Requirements

This subpart contains criteria for determining which substances and ingredients are allowed or prohibited in products to be sold, labeled, or represented as ''organic'' or ''made with organic (specified ingredients or food group(s)).'' It establishes the National List of Allowed and Prohibited Substances (National List) and identifies specific substances which may or may not be used in organic production and handling operations. Sections 6504, 6510, 6517, and 6518 of the Organic Foods Production Act (OFPA) of 1990 provide the Secretary with the authority to develop the National List. The contents of the National List are based upon a Proposed National List, with annotations, as recommended to the Secretary by the National Organic Standards Board (NOSB). The NOSB is established by the OFPA to advise the Secretary on all aspects of the National Organic Program (NOP). The OFPA prohibits synthetic substances in the production and handling of organically produced agricultural products unless such synthetic substances are placed on the National List.

Substances appearing on the National List are designated using the following classifications:

1. Synthetic substances allowed for use in organic crop production
2. Nonsynthetic substances prohibited for use in organic crop production
3. Synthetic substances allowed for use in organic livestock production
4. Nonsynthetic substances prohibited for use in organic livestock production
5. Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food group(s))
6. Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as organic'' or ''made with organic (specified ingredients or food group(s))

This subpart also outlines procedures through which an individual may petition the Secretary to evaluate substances for developing proposed National List amendments and deletions.

The NOSB is responsible for making the recommendation of whether a substance is suitable for use in organic production and handling. The OFPA allows the NOSB to develop substance recommendations and annotations and forward to the Secretary a Proposed National List and any subsequent proposed amendments. We have made every effort to ensure the National List in this final rule corresponds to the recommendations on allowed and prohibited substances made by the NOSB. In developing their recommendations, the NOSB evaluates synthetic substances for the National List utilizing the criteria stipulated by the Act. Additionally, criteria for evaluating synthetic processing ingredients have been implemented by the NOSB. These criteria are an interpretation and application of the general evaluation criteria for synthetic substances contained in the OFPA that the NOSB will apply to processing aids and adjuvants. The NOSB adopted these criteria as internal guidelines for evaluating processing aids and adjuvants. The adopted criteria do not supersede the criteria contained in the OFPA or replace the Food and Drug Administration's (FDA) regulations related to food additives and generally recognized as safe (GRAS) substances. The NOSB has also provided recommendations for the use of synthetic inert ingredients in formulated pesticide products used as production inputs in organic crop or livestock operations. The Environmental Protection Agency (EPA) regulates and maintains the EPA Lists of Inert ingredients used for pesticide. In this final rule, EPA Inerts List 1 and 2 are prohibited, EPA List 3 is also prohibited unless specifically recommended as allowed by the NOSB, and EPA List 4 Inerts are allowed unless specifically prohibited.

In this final rule, only EPA List 4 Inerts are allowed as ingredients in formulated pesticide products used in organic crop and livestock production. The allowance for EPA List 4 Inerts only applies to pesticide formulations. Synthetic ingredients in any formulated products used as organic production inputs, including pesticides, fertilizers, animal drugs, and feeds, must be included on the National List. As sanctioned by OFPA, synthetic substances can be used in organic production and handling as long as they appear on the National List. The organic industry should clearly understand that NOSB evaluation of the wide variety of inert ingredients and other nonactive substances will require considerable coordination between the NOP, the NOSB, and industry. Materials review can be anticipated as one of the NOSB's primary activities during NOP implementation. Considering the critical nature of this task, the organic industry should make a collaborative effort to prioritize for NOSB review those substances that are essential to organic production and handling. The development and maintenance of the National List has been and will be designed to allow the use of a minimal number of synthetic substances that are acceptable to the organic industry and meet the OFPA criteria.

We expect the maintenance of the National List to be a dynamic process. We anticipate that decisions on substance petitions for the inclusion on or deletion from the National List will be made on an annual basis. Any person seeking a change in the National List should request a copy of the petition procedures that were published in the **Federal Register** (65 Fed Reg 43259—43261) on July 13, 2000, from the NOP. The National List petition process contact information is: Program Manager, National Organic Program, USDA/AMS/TMP/NOP, Room 2945–S, Ag Stop 0268, P.O. Box 96456, Washington, DC 20090–6456 or visit the NOP website: www.ams.usda.gov/nop. Substances petitioned for inclusion on the National List will be reviewed by the NOSB, which will forward a recommendation to the Secretary. Any amendments to the National List will require rulemaking and must be published for comment in the **Federal Register**.

Nothing in this subpart alters the authority of other Federal agencies to regulate substances appearing on the National List. FDA issues regulations for the safe use of substances in food production and processing. USDA's Food Safety and Inspection Service (FSIS) has the authority to determine efficacy and suitability regarding the production and processing of meat, poultry, and egg products. FDA and FSIS restrictions on use or combinations of food additives or GRAS substances take precedence over the approved and prohibited uses specified in this final rule. In other words, any combinations of substances in food processing not already addressed in FDA and FSIS regulations must be approved by FDA and FSIS prior to use. FDA and FSIS regulations can be amended from time to time under their rulemaking procedures, and conditions of safe use of food additives and GRAS substances can be revised by the amendment. It is important that certified organic producers and handlers of both crop and livestock products consult with FDA regulations in 21 CFR parts 170 through 199 and FSIS regulations in this regard. All feeds, feed ingredients, and additives for feeds used in the

production of livestock in an organic operation must comply with the Federal Food, Drug, and Cosmetic Act (FFDCA). Animal feed labeling requirements are published in 21 CFR Part 501, and new animal drug requirements and a listing of approved animal drugs are published in 21 CFR parts 510–558. Food (feed) additive requirements, a list of approved food (feed) additives generally recognized as safe substances, substances affirmed as GRAS, and substances prohibited from use in animal food or feed are published in 21 CFR parts 570–571, 21 CFR part 573, 21 CFR part 582, 21 CFR part 584, and 21 CFR part 589, respectively. Furthermore, the Food and Drug Administration has worked closely with the Association of American Feed Control Officials (AAFCO) and recognizes the list of additives and feedstuffs published in the AAFCO Official Publication, which is updated annually.

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA regulates the use of all pesticide products, including those that may be approved for use in the NOP. In registering a pesticide under FIFRA, EPA approves the uses of each pesticide product. It is a violation of FIFRA to use a registered product in a manner inconsistent with its labeling. The fact that a substance is on the National List does not authorize use or a pesticide product for that use if the pesticide product label does not include that use. If the National List and the pesticide labeling conflict, the pesticide labeling takes precedence and may prohibit a practice allowed on the National List.

National List—Changes Based On Comments

This subpart differs from the proposal in several respects as follows:

(1) *Comprehensive Prohibition on Excluded Methods.* Many commenters supported a comprehensive prohibition on the use of excluded methods in organic production and handling. These commenters stated that the proposed language on excluded methods could have allowed some uses since the general prohibition described in section 205.301 of the proposed rule could be interpreted as applying only to multiingredient products. In order to provide a comprehensive prohibition on the use of excluded methods, we incorporated a new provision within section 205.105. A more comprehensive discussion of this issue is found in subpart B, Applicability.

(2) *Substance Evaluation Criteria for the National List.* Commenters stated that the final rule should include in the regulation text the evaluation criteria utilized by the NOSB for the development of substance recommendations. We agree, and we have inserted the substance evaluation criteria developed by the NOSB for processing ingredients and cited the criteria within the Act (7 U.S.C. 6518(m)) for crops and livestock production as new provisions for section 205.600, which is now entitled ''Evaluation criteria for allowed and prohibited substances, methods, and ingredients.''

(3) *Substances Approved for Inclusion on the National List.* Commenters stated that the National List did not contain all of the substances recommended by the NOSB for inclusion on the National List of Allowed and Prohibited Substances. We agree and have added the following substances consistent with the most recent NOSB recommendations:

Crop Production

Lime sulfur as a plant disease control substance

Elemental sulfur as a plant or soil amendment

Copper as a plant or soil micronutrient

Streptomycin sulfate as plant disease control substances with the annotation '' for fire blight control in apples and pears only''

Terramycin (oxytetracycline calcium complex) as a plant disease control substance with the annotation ''for fire blight control only''

Magnesium sulfate as a plant or soil amendment with the annotation ''allowed with a documented soil deficiency''

Ethylene as a plant growth regulator, with the annotation ''for regulation of pineapple flowering''

We have added sodium nitrate and potassium chloride to the National List as nonsynthetic substances prohibited for use in crop production unless used in accordance with the substance annotations. Sodium nitrate is prohibited unless use is restricted to no more than 20 percent of the crop's total nitrogen requirement. Potassium chloride is prohibited unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil. These additions are discussed further in item 3 under Changes Based on Comments, subpart C.

Livestock Production

Oxytocin with the annotation ''for use in postparturition therapeutic applications''

EPA List 4 inert ingredients as synthetic inert ingredients for use with nonsynthetic substances or synthetic substances allowed in organic livestock production.

Several commenters recommended that the final rule should specify which nonsynthetic substances are prohibited for use in livestock production. These commenters stated that the proposed rule prohibited six such substances for use in crop production and maintained that an analogous list for livestock operations would be beneficial. Of the six nonsynthetic substances in the proposed rule prohibited for use in crop production, four were based on NOSB recommendations (strychnine, tobacco dust, sodium fluoaluminate (mined), and ash from burning manure) and two were based on statutory provisions in the OFPA (arsenic and lead salts). After reviewing these substances and the NOSB recommendations, we determined that the prohibition for one, strychnine, also applies to livestock production. Individuals may petition the NOSB to have additional nonsynthetic substances prohibited for use in organic crop and livestock production.

Organic Handling (Processing)

Tribasic calcium phosphate

Nonsynthetic colors

Flavors, with the annotation ''nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservatives''

Nonsynthetic waxes, carnauba wax, wood resin

Cornstarch (native), gums, kelp, lecithin and pectin were moved from section 205.605 to section 205.606

(4) *Substance Removed from the National List.* Commenters stated that certain substances on the National List in the proposed rule had not been recommended by the NOSB. We agree with the comment that the NOSB did not recommend that magnesium should be allowed as a plant or soil micronutrient and have removed it from the National List.

(5) *Changes in Substance Annotations on the National List.* Commenters stated that certain annotations in the proposed rule did not capture the precise recommendations of the NOSB. We agree and have amended the annotations within the National List as follows:

The annotation for hydrated lime as a plant disease control substance now states, ''must be used in a manner that minimizes accumulation of copper in the soil.''

The annotation for horticultural oils as an insecticide substance and as a plant disease control substance now

states, ''Narrow range oils as dormant, suffocating, and summer oils.''

The annotation for hydrated lime in livestock production now states, ''not permitted for soil application or to cauterize physical alterations or deodorize animal wastes.''

The annotation for the allowed synthetic parasiticide Ivermectin has been modified to state that the substance may not be used during the lactation period of breeding stock.

The annotation for trace minerals and vitamins allowed as feed additives has been modified and now states, ''used for enrichment or fortification when FDA approved.''

The annotation for magnesium sulfate in organic handling now states, ''nonsynthetic sources only.''

The annotation for EPA List 4 Inerts allowed in crop and livestock production has been modified to state, '' * * * for use with nonsynthetic substances or synthetic substances listed in this section * * *''

(6) *Sulfur Dioxide for Organic Wines.* Many commenters recommended that this final rule should allow for the use of sulfur dioxide in wine labeled ''made with organic grapes.'' They argued that sulfur dioxide is necessary in organic wine production and that prohibiting its use would have a negative impact on organic grape production and wineries that produce wine labeled ''made with organic grapes.'' The prohibition on the use of sulfur dioxide in the proposed rule was based upon the requirement in the Act that prohibited the addition of sulfites to organically produced foods. However, a change in the Act now allows the use of sulfites in wine labeled as ''made with organic grapes.'' Therefore, we have added sulfur dioxide to the National List with the annotation, ''for use only in wine labeled ''made with organic grapes,'' Provided, That, total sulfite concentration does not exceed 100 ppm.'' The label for the wine must indicate the presence of sulfites. This addition to the National List is also in agreement with the NOSB recommendation for allowing the use of sulfur dioxide in producing wine to be labeled as ''made with organic grapes.''

National List—Changes Requested But Not Made

This subpart retains from the proposed rule regulations on which we received comments as follows:

(1) *Restructuring the National List.* Commenters requested a restructuring of the National List to improve its clarity and ease of use. Some of the commenters asked for minor changes involving the wording of section titles. Other commenters were opposed to the categories used in the National List because the categories are not in compliance with the Act. In its June 2000 meeting, the NOSB asked the NOP to review a proposal from a research institute proposing that processing materials for the National List be categorized according to industry standards. This proposal recommended including new sections for substances used in ''made with * * *'' and substances used in the 5-percent nonorganic portion of ''organic'' multiingredient products. We agree that the present structure of the National List may not have optimum clarity and ease of use. However, extensive restructuring of the National List without additional NOSB consideration and public discussion would be a significant variation from the policy that established the National List for this final rule. The NOP will work with the NOSB and the public to refine the National list consistent with industry norms and public expectations.

(2) *Use of EPA List 4 Inerts.* The proposed rule allowed EPA List 4 Inerts to be used as synthetic inert ingredients with allowed synthetic active ingredients in crop production. Some commenters stated that certain substances among the EPA List 4 inerts should not be allowed in organic production. Some commenters went further and recommended that the allowance for synthetic inert ingredients should be limited to the subset of materials that the EPA designates as List 4A. We do not agree with these commenters and have retained the allowance for all inerts included on EPA List 4. List 4 inerts are classified by EPA as those of ''minimal concern'and, after continuing consultation with EPA, we believe there is no justification for a further restriction to List 4A. If commenters believe that a particular List 4 inert should not be allowed in formulated products used in organic production, they can petition the NOSB to have that substance prohibited.

(3) *Removing Vaccines from the National List.* Some commenters asserted that vaccines should not be included on the National List because the NOSB had never favorably recommended their use in livestock production. However, the OFPA authorizes the use of vaccines, and in 1995, the NOSB recommended allowing their use. The NOSB stated that use of vaccines may be necessary to ensure the health of the animal and to remain in compliance with Federal, State, or regional regulations. We agree with the NOSB's recommendation and have retained vaccines as an allowed substance in livestock medication.

(4) *Adding Amino Acids to the National List.* Some commenters recommended that amino acids should be added to the National List as allowed synthetic substances for livestock production. We have not added amino acids to the National List because the NOSB has not recommended that they should be allowed. This subject is discussed further in item 4, Livestock—Changes Based on Comments, subpart C.

(5) *Creating a Category for Prohibited Nonsynthetic Seed Treatments.* A commenter stated that the National List of nonsynthetic substances prohibited for use in crop production should include provisions for seed treated with a nonsynthetic substance. This commenter stated that the final rule should acknowledge that a nonsynthetic seed treatment could be prohibited on the National List. We do not believe it is necessary to include a separate category for seed treatments under the prohibited nonsynthetic section of the National List. An individual may petition the NOSB to have a particular nonsynthetic seed treatments placed on the prohibited list without creating a new category for seed treatments.

(6) *Creating a Category for Treated Seed and Toxins Derived from Bacteria.* Commenters stated that the National List of synthetic substances allowed in crop production should include categories for treated seed and toxins derived from bacteria. These commenters stated that these categories are sanctioned by the OFPA, and failure to consider them would place a significant burden on organic producers. We believe it is unnecessary to include these categories on the National List. Specific substances from these categories could be incorporated in existing categories that reflect their function, such as plant disease control or insecticide. An individual may submit petitions to the NOSB to have specific substances from these categories considered for inclusion on the National List.

(7) *Remove Categories for Feed Supplements.* A commenter stated that it was inappropriate for the National List of synthetic substances allowed in livestock production to contain categories for feed supplements and feed additives because they are not authorized in the OFPA. We disagree with this commenter because the identification of categories on the National List does not mean that all substances within that category are allowed. The categories help to clarify which types of materials may be included on the National List. The substances included under the categories of feed supplements and feed

additives were recommended by the NOSB and added to the National List with the Secretary's approval.

(8) *Neurotoxic Substances on the National List.* Many commenters requested that the NOP remove particular substances from section 205.605 of the National List. They stated these substances were sources of neurotoxic compounds that negatively effect human health. The substances cited were yeast (autolysate and brewers), carrageenan, and enzymes. Moreover, these commenters argued against including on the National List some amino acids or their derivatives which the commenters claim have neurotoxic side effects. These commenters requested that amino acids should be prohibited from the National List due to the possibility that neurotoxic substances could be utilized for either organic agricultural production or handling.

We do not agree with the requests of the commenters and we have not made the requested changes. There are no amino acids currently on the National List; therefore, synthetic sources of amino acids are prohibited. Unless recommended for use by the NOSB, synthetic amino acids will not be included on the National List. The NOP has established a petition process for substances to be evaluated for inclusion on or removal from the National List of Allowed and Prohibited Substances in organic production and handling. Anyone seeking to have a particular substance removed from the National List may file a substance petition to amend the National List.

(9) *EPA List 4 Inerts for Organic Processing.* A few commenters recommended that substances in EPA List 4 inerts that are allowed for use in crop production also be allowed for use as processing materials. We do not agree, and we have not included EPA List 4 Inerts on the National List for organic handling. Inerts listed on EPA List 4 have been evaluated and approved for use in pesticide formulations, not for use as processing materials. Inerts that are included on EPA List 4 would have to be further evaluated to determine whether such materials meet the criteria for inclusion on the National List.

(10) *Modifying Annotations of Organic Processing Substances.* One commenter requested that the Department modify the annotation for phosphoric acid to include its use as a processing aid. We have not made the suggested change. Any change in the annotation of a substance can only occur through an NOSB recommendation. Individuals or groups can use the petition process to submit substance petitions to the NOSB for the evaluation to be included on or removed from the National List.

(11) *Nutritional Supplementation of Organic Foods.* Some commenters asserted that 21 CFR 104.20 is not an adequate stand-alone reference for nutritional supplementation of organic foods. As a result, these commenters recommended that the final rule include as additional cites 21 CFR 101.9(c)(8) for FDA-regulated foods and 9 CFR 317.30(c), 318.409(c)(8) for foods regulated by FSIS to support 21 CFR 104.20. We did not implement the suggested changes of the commenters. Section 205.605(b)(20) in the proposed rule allowed the use of synthetic nutrient vitamins and minerals to be used in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods, as ingredients in processed products to be sold as ''organic'' or ''made with * * *.'' The commenters recommended cites, 21 CFR 101.9(c)(8) for FDA-regulated foods and 9 CFR 317.30(c); section 318.409(c)(8) did not provide provisions for nutritional supplementation of foods. Instead, these suggested cites were particularly aimed toward: (1) The declaration of nutrition information on the label and in labeling of a food; (2) labeling, marking devices, and containers; (3) entry into official establishments; and (4) reinspection and preparation of products. The NOP, in consultation with FDA, considers 21 CFR 104.20 to be the most appropriate reference regarding nutritional supplementation for organic foods.

(12) *National List Petition Process as Part of the Final Rule.*

Commenters have requested that the National List Petition Process, approved by the NOSB at its June 2000 meeting (and published in the **Federal Register** on July 13, 2000), be included in the final rule. We do not agree with the commenters, and we have retained the National List Petition Process regulation language from the proposed rule. We have separated the specific petition process from the regulation to provide for maximum flexibility to change and clarify the petition process to accommodate new considerations developed during the NOP implementation. If this process were part of this final rule, updates to the petition process would require notice and comment rulemaking. Any changes in the National List that may be a result of the petition process, however, would require notice and comment rulemaking.

(13) *Nonapproved Substance Amendments to the National List.* Commenters also requested to have many substances that are not on the National List and that have not been recommended by the NOSB for use in organic production and handling be added to the National List. We do not agree. Amendments to the National List must be petitioned for NOSB consideration, must have an NOSB recommendation, and must be published for public comment in the **Federal Register**.

National List—Clarifications

Clarification is given on the following issues raised by commenters as follows:

(1) *Inerts Use in Botanical or Microbial Pesticides.* Commenters expressed concern that the prohibition on the use of EPA List 3 inerts would prevent organic producers from using certain botanical or microbial formulated products that are currently allowed under some certification programs. These commenters requested that the NOP and the NOSB expedite the evaluation of List 3 inerts used in nonsynthetic formulated products to prevent the loss of certain formulated products. The prohibition of List 3 inerts was based on the recommendation of the NOSB to add only those substances from List 4 to the National List. The NOSB also recommended that individual inert substances included on List 3 could be petitioned for addition to the National List. The NOP has requested that the NOSB identify for expedited review those List 3 inerts that are most important in formulated products used in organic production. Individuals may petition to have these inerts considered for inclusion on the National List. Additionally, the NOP will work with the EPA and the registrants of formulated products to expedite review of List 3 inerts currently included in formulated products used in organic production. Unless List 3 inerts are moved to List 4 or individually added to the National List, they are prohibited for use in organic production.

(2) *Prohibiting Ash, Grit, and Screenings Derived from Sewage Sludge.* Many commenters recommended that the ash, grit, and screenings derived from the production of sewage sludge should be added to the National List as nonsynthetic materials prohibited for use in crop production. While the use of sewage sludge, including ash, grit, and screenings, is prohibited in organic production, we did not add them to the National List as prohibited nonsynthetic substances. This subject is discussed further under subpart A, Definitions—Changes Requested But Not Made.

(3) *Allowed Uses for Pheromones.* Some commenters were concerned that

the annotation for using pheromones as ''insect attractants'' was too limiting and would not include uses such as mating disruption, trapping, and monitoring. The annotation for pheromones does not preclude any use for a pheromone that is otherwise allowed by Federal, State, or local regulation.

(4) *Nonagricultural Products as Livestock Feed Ingredients.* Some commenters questioned whether nonsynthetic, nonagricultural substances such as fishmeal and crushed oyster shell needed to be added to the National List to be used in livestock feed. Nonsynthetic substances do not have to appear on the National List and may be used in organic livestock feed, provided that they are used in compliance with the FFDCA. This subject is discussed further under item 4, Livestock—Changes Based on Comments, subpart C.

(5) *Chlorine Disinfectant Limit Annotation for Organic Production and Handling.* Some commenters requested clarification on the annotation for using chlorine materials as an allowed synthetic substance in crop and handling operations. The annotation in the proposed rule, which has been retained in the final rule, stated that ''residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Water Drinking Act.'' With this annotation, the residual chlorine levels at the point where the waste water stream leaves the production or handling operation must meet limits under the Safe Drinking Water Act.

(6) *Tobacco Use in Organic Production.* One commenter questioned whether forms of tobacco other than tobacco dust, such as water extracts or smoke, were prohibited nonsynthetic substances. The technical advisory panel (TAP) review on which the NOSB based its recommendation to prohibit tobacco dust identified nicotine sulfate as the active ingredient. Therefore, any substance containing nicotine sulfate as an active ingredient is prohibited in crop production.

(7) *Nonsynthetic Agricultural Processing Aids on the National List.* A commenter requested clarification from the NOP on whether processing aids (*e.g.,* defoaming agents), which are nonsynthetic and nonorganic agricultural substances (*e.g.,* soybean oil), must appear on the National List when used in processing. In the regulation, a nonsynthetic and nonorganic agricultural product, such as soybean oil, used as a processing aid does not have to appear on the National List. Such products are included in the provision in section 205.606 that nonorganically produced agricultural products may be used in accordance with any applicable restrictions when the substance is not commercially available in organic form.

(8) *Transparency of the National List Petition Process.* Some commenters stated the petition process for amending the National List appears to have limited public access and should be more transparent. These commenters advocate that any amendments to the National List should be subject to notice and comment. They also requested clarity on how petitions are prioritized and reviewed and the timeframes for review. Additionally, these commenters asked the NOP to expedite the review of materials for the National List. On July 13, 2000, AMS published in the **Federal Register** (Vol. 65, 43259–43261) guidelines for submitting petitions for the evaluations of substances for the addition to or removal from the National List. In this notice, the NOP stated that most petition information is available for public inspection with the exception of information considered to be ''confidential business information.'' The notice also specified that any changes to the National List must be published in the **Federal Register** for public comment. The published petition notice has also provided an indication to the industry about the urgency of the need for substance review and that the industry should provide pertinent information to the NOSB to expedite the review of materials not on the National List.

State Organic Programs

The Act provides that each State may implement an organic program for agricultural products that have been produced and handled within the State, using organic methods that meet the requirements of the Act and these regulations. The Act further provides that a State organic program (SOP) may contain more restrictive requirements for organic products produced and handled within the State than are contained in the National Organic Program (NOP). All SOP's and subsequent amendments thereto must be approved by the Secretary.

A State may have an SOP but not have a State certifying agent. A State may have a State certifying agent but no SOP. Finally, a State may have an SOP and a State certifying agent. In all cases, the SOP's must be approved by the Secretary. In all cases, the State certifying agent must apply for and receive accreditation to certify organic production or handling operations pursuant to subpart F.

In States with an approved SOP, the SOP's governing State official is responsible for administering a compliance program for enforcement of the NOP and any more restrictive requirements contained in the SOP. The SOP governing State officials may review and investigate complaints of noncompliance involving organic production or handling operations operating within their State and, when appropriate, initiate suspension or revocation of certification. The SOP governing State officials may also review and investigate complaints of noncompliance involving accredited certifying agents operating within their State. They must report the findings of any review and investigation of a certifying agent to the NOP Program Manager along with any recommendations for appropriate action. States that do not have an SOP will not be responsible for compliance under the NOP, except that an accredited State certifying agent operating within such State will have compliance responsibilities under the NOP as a condition of its accreditation.

The sections covering SOP's, beginning with section 205.620, establish: (1) The requirements for an SOP and amending such a program and (2) the process for approval of an SOP and amendments to the SOP's. Review and approval of an SOP will occur not less than once during each 5-year period. Review related to compliance matters may occur at any time.

Description of Regulations

State Organic Program Requirements

A State may establish an SOP for production and handling operations within the State that produces and handles organic agricultural products. The SOP and supporting documentation must demonstrate that the SOP meets the requirements for organic programs specified in the Act.

An SOP may contain more restrictive requirements governing the production and handling of organic products within the State. Such requirements must be based on environmental conditions or specific production or handling practices particular to the State or region of the United States, which necessitates the more restrictive requirement. More restrictive requirements must be justified and shown to be consistent with and to further the purposes of the Act and the regulations in this part. Requirements necessitated by an environmental condition that is limited to a specific geographic area of the State should only be required of organic production and

handling operations operating within the applicable geographic area. If approved by the Secretary, the more restrictive requirements will become the NOP regulations for organic producers and handlers in the State or applicable geographical area of the State. All USDA-accredited certifying agents planning to operate within a State with an SOP will be required to demonstrate their ability to comply with the SOP's more restrictive requirements.

No provision of an SOP shall discriminate against organic agricultural products produced by production or handling operations certified by certifying agents accredited or accepted by USDA pursuant to section 205.500. Specifically, an SOP may not discriminate against agricultural commodities organically produced in other States in accordance with the Act and the regulations in this part. Further, an SOP may not discriminate against agricultural commodities organically produced by production or handling operations certified by foreign certifying agents operating under: (1) Standards determined by USDA to meet the requirements of this part or (2) an equivalency agreement negotiated between the United States and a foreign government.

To receive approval of its SOP, a State must assume enforcement obligations in the State for the requirements of this part and any more restrictive requirements included in the SOP and approved by the Secretary. Specifically, the State must ensure compliance with the Act, the regulations in this part, and the provisions of the SOP by certified production and handling operations operating within the State. The SOP must include compliance and appeals procedures equivalent to those provided for under the NOP.

An SOP and any amendments thereto must be approved by the Secretary prior to implementation by the State.

State Organic Program Approval Process

An SOP and subsequent amendments thereto must be submitted to the Secretary by the SOP's governing State official for approval prior to implementation. A request for approval of an SOP must contain supporting materials that include statutory authorities, program descriptions, documentation of environmental or ecological conditions or specific production and handling practices particular to the State which necessitate more restrictive requirements than the requirements of this part, and other information as may be required by the Secretary. A request for amendment of an approved SOP must contain supporting materials that include an explanation and documentation of the environmental or ecological conditions or specific production practices particular to the State or region, which necessitate the proposed amendment. Supporting material also must explain how the proposed amendment furthers and is consistent with the purposes of the Act and the regulations in this part.

Each request for approval of an SOP or amendment to an SOP and its supporting materials and documentation will be reviewed for compliance with the Act and these regulations. Within 6 months of receiving the request for approval, the Secretary will notify the SOP's governing State official of approval or disapproval. A disapproval will include the reasons for disapproval. A State receiving a notice of disapproval of its SOP or amendment to its SOP may submit a revised SOP or amendment to its SOP at any time.

Review of State Organic Programs

SOP's will be reviewed at least once every 5 years by the Secretary as required by section 6507(c)(1) of the Act. The Secretary will notify the SOP's governing State official of approval or disapproval of the program within 6 months after initiation of the review.

State Organic Programs—Changes Based on Comments

This portion of subpart G differs from the proposal in several respects as follows:

(1) *Publication of SOP's and Consideration of Public Comments.* Some commenters assert that the USDA should not publish SOP provisions for public comment in the **Federal Register**. These commenters argued that it is not appropriate for the NOP to have nonresidents commenting on a particular State program as nearly all States have a mechanism to ensure full public participation in their regulation promulgation. They believe the comment process set forth in the proposed rule is a redundant and unacceptable intrusion on State sovereignty.

We will not publish for public comment the provisions of SOP's under review by the Secretary in the **Federal Register**. We have removed the provision from this final rule, described in section 205.621(b), requiring the Secretary to publish in the **Federal Register** for public comment a summary of the SOP and a summary of any amendment to such a program. Alternatively, we will announce which SOP's are being reviewed through the NOP website. The NOP will issue public information notices that will announce each approved SOP and any approved amendments to an existing State program. The notices will identify the characteristics of the approved State program that warranted the more restrictive organic production or handling requirements. We also will include a summary of the new program on the NOP website.

(2) *NOP Oversight of SOP's.* Several commenters stated that, in the proposed rule, the provisions did not provide a comprehensive description of organic programs operated by States that would be under NOP authority. Some commenters implied that the proposed rule would only include States with organic certification programs, while other commenters inquired whether the sections 205.620 to 205.622 included other SOP activities beyond certification.

To address the commenters' concerns, we have modified the section heading by adding the term, ''organic,'' and removing the term, ''certification,'' from the description and definition of SOP's. We have taken this action to clarify that, while certification is one component of the requirements, it does not define the extent of evaluation of State programs that will be conducted by the NOP. SOP's can choose not to conduct certification activities under their existing organic program. State programs whose provisions fall within the scope of the eleven general provisions described in the Act (7 U.S.C. 6506) will require Departmental review.

States may conduct other kinds of organic programs that will not need review and approval by the NOP. Examples of these other programs may include: organic promotion and research projects, marketing; transition assistance or cost share programs, registration of State organic production and handling operations, registration of certifying agents operating within the State, or a consumer referral program. The NOP will not regulate such State activities. Such programs may not advertise, promote, or otherwise infer that the State's organic products are more organic or better than organic product produced in other States. Such programs and projects would be beyond the scope of this national program and will not be subject to the Secretary's review.

State Organic Programs—Changes Requested But Not Made

(1) *Limitations on SOP More Restrictive Requirements.* Commenters expressed concern that limiting a State's

ability to craft a regulation designated as a more restrictive requirement to environmental conditions or specific production and handling practices would hinder the ongoing development of SOP's. They were concerned that any State legislation modifying the SOP would need to be preapproved by the Secretary.

We have retained the provision limiting the scope of more restrictive requirements States can include in their organic program as described in section 205.620(c). We believe the language contained in the provision is broad enough to facilitate the development of SOP's without hindering development or State program implementation and enforcement. Section 6507(b)(1) of the Act provides that States may establish more restrictive organic certification requirements; paragraph (b)(2) establishes parameters for those requirements. More restrictive SOP requirements must: further the purposes of the Act, be consistent with the Act, not discriminate against other State's agricultural commodities, and be approved by the Secretary before becoming effective. We expect that a State's more restrictive requirements are likely to cover specific organic production or handling practices to address a State's specific environmental conditions. The Secretary will approve State's requests for more restrictive State requirements that are consistent with the purposes of the Act. However, we believe requests from States for more restrictive requirements will be rare. Although SOP's can impose additional requirements, we believe States will be reluctant to put their program participants at a competitive disadvantage when compared to producers and handlers in other States absent compelling environmental conditions or a compelling need for special production and handling practices. While preapproval of State legislation modifying an existing SOP is not required, the NOP envisions a close consultation with States with existing programs to ensure consistency with the final rule.

(2) *SOP Enforcement Obligations.* Some commenters expressed concern about States having adequate resources available to implement enforcement activities that they are obligated to conduct under the NOP. A few of these commenters argue that the enforcement obligation will result in their State programs being discontinued. A few commenters cited a lack of federal funding to support State enforcement obligations and suggested the NOP provide funding for enforcement activities.

The proposed rule indicated that States with organic programs must assume enforcement obligations for this regulation within their State. We have retained this enforcement obligation in section 205.620(d). Many States currently have organic programs with the kind of comprehensive enforcement and compliance mechanisms necessary for implementing any State regulatory program. Assuming those enforcement activities are consistent with the NOP, this final rule adds no additional regulatory burden to the SOP's. The costs associated with the enforcement activities of an approved SOP should be similar to the enforcement costs associated with the existing State program. Additional clarification of SOP enforcement obligations is in the Accreditation, Appeals, and Compliance preamble discussions.

(3) *SOP Evaluation Notification Period.* A few commenters indicated that the SOP review and decision notification period described in section 205.621(b) of the proposed rule could hinder a State's ability to develop or implement an SOP. These commenters cited potential cases in which particular States have requirements for regulatory promulgation that must occur within 6 months under a State legislative session that is held once every 2 years. These commenters suggested the NOP should reduce the notification time to 1 to 3 months.

We disagree with the commenters. In the proposed rule in section 205.621(b), the Secretary is required to notify the SOP's governing State official within 6 months of receipt of submission of documents and information regarding the approval of the SOP. We have retained this time period. We will review SOP applications as quickly as possible and will endeavor to make decisions in less than 6 months whenever possible. However, some SOP's may be very complex and require more review time. The NOP envisions working closely with the States and State officials to ensure a smooth transition to the requirements of this final rule.

State Organic Programs—Clarifications

(1) *Discrimination Against Organic Products.* Several commenters requested the addition of a provision prohibiting an SOP from discriminating against agricultural commodities organically produced in other States. Discrimination by a State against organically produced agricultural products produced in another State is prevented in two ways. First, any organic program administered by a State must meet the requirements for organic programs specified in the Act and be approved by the Secretary. Finally, a USDA-accredited certifying agent must accept the certification decisions made by another USDA-accredited certifying agent as its own.

(2) *Potential Duplication Between the Accreditation and SOP Review Process.* Some commenters asked about possible duplication between the process for reviewing SOP's and the process of accreditation review. These commenters have asked the NOP to eliminate any duplication that may exist between the two review processes. The NOP will be conducting a review process for SOP's and a separate review process for accrediting State and private certifying agents. The two reviews are different. The SOP review is the evaluation of SOP compliance with the Act and the NOP regulations. If approved, the SOP becomes the NOP standards for the particular State with which all certifying agents operating in that State must comply. Approved SOP's must be in compliance with the Act and the NOP regulations. They cannot have weaker standards than the NOP. States can have more restrictive requirements than the NOP if approved by the Secretary.

The accreditation review is an evaluation of the ability of certifying agents to carry out their responsibilities under the NOP. This review is a measure of the competency of certifying agents to evaluate compliance to national organic standards. Certifying agents will not be unilaterally establishing regulations or standards related to the certification of organic products. They will only provide an assessment of compliance.

Thus, SOP reviews and accreditation reviews are separate evaluations of different procedures. We acknowledge some of the information for the two evaluations may be similar; *e.g.,* compliance procedures. The reviews do not duplicate the same requirements. However, the NOP envisions working with States to ensure documentation is not duplicated.

(3) *Scope of Enforcement by States.* A number of State commenters have requested clarification on the proposed rule provision specifying that approved SOP's must assume enforcement obligations in their State for the requirements of the NOP and any additional requirements approved by the Secretary. These commenters have indicated that they remain uncertain as to what is expected by the term, ''enforcement obligation.''

Approved SOP's will have to administer and provide enforcement of the requirements of the Act and the

regulations of the NOP. The administrative procedures used by the State in administering the approved SOP should have the same force and effect as the procedures use by AMS in administering this program. This final rule specifies that the requirements for environmental conditions or for special production and handling practices are necessary for establishing more restrictive requirements. These factors establish our position that a State must agree to incurring increased enforcement responsibilities and obligations to be approved as an SOP under the NOP. For instance, a State with an approved organic program will oversee compliance and appeals procedures for certified organic operations in the State. Those procedures must provide due process opportunities such as rebuttal, mediation, and correction procedures. Once approved by the Secretary, the State governing official of the SOP must administer the SOP in a manner that is consistent and equitable for the certified parties involved in compliance actions.

(4) *SOP's That Do not Certify and NOP Oversight.* A few commenters requested that the NOP develop new provisions to include State programs that have organic regulations but do not conduct certification activities. These commenters argue that any SOP that has a regulatory impact on organic producers, regardless of whether or not the program includes certification, be approved by the Secretary.

This regulation, in section 205.620(b), provides for NOP oversight of SOP's that do not conduct certification activities.

(5) *State's Use of Private Certifying Agents.* Some commenters have requested that the NOP provide clarification of the proposed rule sections 205.620 through 205.622 on how these sections will affect States that delegate certification activities to private certifying agents. These commenters asked how the NOP intends to oversee this type of State activity.

The NOP intends to give considerable latitude to States in choosing the most appropriate system or procedures to structure their programs. This may include a State establishing its own certifying agent or relying on private certifying agents. However, States will not be accrediting certifying agents operating in their State. Accreditation of all certifying agents operating in the United States is the responsibility of USDA. Establishment of a single national accreditation program is an essential part of the NOP. As stated elsewhere in this final rule, any accreditation responsibilities of a State's current organic program will cease with implementation of this program. Pursuant to the Compliance provisions of this subpart, the governing State official charged with compliance oversight under the SOP may investigate and notify the NOP of possible compliance violations on the part of certifying agents operating in the State. However, the State may not pursue compliance actions or remove accreditation of any certifying agent accredited by the Secretary. That authority is the sole responsibility of the Secretary. If more restrictive State requirements are approved by the Secretary, we will review certifying agent qualifications in the State, as provided by section 205.501(a)(20), and determine whether they are able to certify to the approved, more restrictive requirements. Our accreditation responsibilities include oversight of both State and private certifying agents, including any foreign certifying agents that may operate in a State.

Subpart G—Fees

This portion of subpart G sets forth the regulations on fees and other charges to be assessed for accreditation and certification services under the National Organic Program (NOP). These regulations address the kinds of fees and charges to be assessed by the U.S. Department of Agriculture (USDA) for the accreditation of certifying agents, the level of such fees and charges, and the payment of such fees and charges. These regulations also address general requirements to be met by certifying agents in assessing fees and other charges for the certification of producers and handlers as certified organic operations. Finally, these regulations address the Secretary's oversight of a certifying agent's fees and charges for certification services.

Description of Regulation

Fees and Other Charges for Accreditation

Fees and other charges will be assessed and collected from applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation. Such fees will be equal as nearly as may be to the cost of the accreditation services rendered under these regulations. Fees-for-service will be based on the time required to render the service provided calculated to the nearest 15–minute period. Activities to be billed on the basis of time used include the review of applications and accompanying documents and information, evaluator travel, the conduct of on-site evaluations, review of annual reports and updated documents and information, and the preparation of reports and any other documents in connection with the performance of service. The hourly rate will be the same as that charged by the Agricultural Marketing Service (AMS), through its Quality System Certification Program, to certification bodies requesting conformity assessment to the International Organization for Standardization ''General Requirements for Bodies Operating Product Certification Systems'' (ISO Guide 65).

Applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation during the first 18 months following the effective date of subpart F will receive service without incurring an hourly charge for such service.

Applicants for initial accreditation and renewal of accreditation must pay at the time of application, effective 18 months following the effective date of subpart F, a nonrefundable fee of $500.00. This fee will be applied to the applicant's fees-for-service account.

When service is requested at a place so distant from the evaluator's headquarters that a total of one-half hour or more is required for the evaluator(s) to travel to such a place and back to the headquarters or from a place of prior assignment on circuitous routing requiring a total of one-half hour or more to travel to the next place of assignment on the circuitous routing, the charge for such service will include all applicable travel charges. Travel charges may include a mileage charge administratively determined by USDA, travel tolls, or, when the travel is made by public transportation (including hired vehicles), a fee equal to the actual cost thereof. If the service is provided on a circuitous routing, the travel charges will be prorated among all the applicants and certifying agents furnished the service involved. Travel charges will become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F. The applicant or certifying agent will not be charged a new mileage rate without notification before the service is rendered.

When service is requested at a place away from the evaluator's headquarters, the fee for such service shall include a per diem charge if the employee(s) performing the service is paid per diem in accordance with existing travel regulations. Per diem charges to applicants and certifying agents will cover the same period of time for which

the evaluator(s) receives per diem reimbursement. The per diem rate will be administratively determined by USDA. Per diem charges shall become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F. The applicant or certifying agent will not be charged a new per diem rate without notification before the service is rendered.

When costs, other than fees-for-service, travel charges, and per diem charges, are associated with providing the services, the applicant or certifying agent will be charged for these costs. Such costs include but are not limited to equipment rental, photocopying, delivery, facsimile, telephone, or translation charges incurred in association with accreditation services. The amount of the costs charged will be determined administratively by USDA. Such costs will become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F.

Payment of Fees and Other Charges

Applicants for initial accreditation and renewal of accreditation must remit the nonrefundable fee along with their application. Remittance must be made payable to the Agricultural Marketing Service, USDA, and mailed to: Program Manager, USDA–AMS–TMP–NOP, Room 2945-South Building, P.O. Box 96456, Washington, DC 20090–6456 or such other address as required by the Program Manager. All other payments for fees and other charges must be received by the due date shown on the bill for collection, made payable to the Agricultural Marketing Service, USDA, and mailed to the address provided on the bill for collection. The Administrator will assess interest, penalties, and administrative costs on debts not paid by the due date shown on a bill for collection and collect delinquent debts or refer such debts to the Department of Justice for litigation.

Fees and Other Charges for Certification

Fees charged by a certifying agent must be reasonable, and a certifying agent may charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. The certifying agent must provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee that must be applied to the applicant's fees-for-service account. A certifying agent may set the nonrefundable portion of certification fees; however, the nonrefundable portion of certification fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process the respective fees become nonrefundable. The certifying agent must provide all persons inquiring about the application process with a copy of its fee schedule.

Fees—Changes Based on Comments

This subpart differs from the proposal in the following respects:

Nonrefundable Portion of Certification Fees. Commenters were not satisfied with the provision in section 205.642 that stated, ''The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee of no more than $250.00, which shall be applied to the applicant's fee for service account.'' Some commenters believed we were requiring the certifying agents to bill fees for inspection services separately. One State agency expressed a concern that we were placing a limit on the initial fee the certifying agent could collect. As a result, the State agency commented that by not being allowed to collect the full certification fee at the time of application, the certifying agent, in effect, would be extending credit to the applicant. Commenters reported that some State agencies are prevented by statute from extending credit and are required to collect all fees at the time of application. Several commenters stated that the amount of $250.00 was too low and would not cover the costs the certifying agents could incur during the certification process. One organization noted that we should consider prorating the amount of the fee to be refunded when an applicant for certification withdraws before the completion of the certification process. The organization recommended that the amount of the prorated fee should be based on how far along in the certification process the applicant had progressed before withdrawal. Another commenter believed it was inappropriate for USDA to set any fees for private certification programs and that the fees should be market driven.

It was not our intent to limit the initial amount that certifying agents could collect from the applicant for certification. Our intent was to limit the portion of the fee that would be nonrefundable in order to reduce the potential liability for the small producer/handler who may need to withdraw prematurely from the certification process. However, we acknowledge that this provision could be misinterpreted. We also realize that certifying agents may incur initial costs during the preliminary stage of the certification process that may be more or less than the $250.00 application rate proposed. As a result, we have removed the provision that stated certifying agents could collect a nonrefundable fee of not more than $250.00 at the time of application from applicants for certification.

Certifying agents may set the nonrefundable portion of their certification fees. However, the nonrefundable portion of their certification fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process the respective fees become nonrefundable. Certifying agents will also provide all persons inquiring about the application process with a copy of its fee schedule.

Fees—Changes Requested But Not Made

This subpart retains from the proposed rule regulations on which we received comments as follows:

(1) *Farm Subsidy/Transition Program.* Many commenters asked that USDA subsidize or develop a cost-share program for small farmers/producers who are certified or who are in transition to organic farming. Some commenters wanted these costs to be fully subsidized; a few commenters suggested that USDA pay for any extra site visit costs; and many others wanted USDA to pay premium prices to farmers for their products during the period of transition to organic production. In addition, many commenters argued that USDA should fully fund certification costs. Finally, many commenters suggested that the USDA should provide additional financial support to the organic industry because the industry is relatively young and composed of a large number of small, low-resource businesses.

We have considered the commenters requests but have not made the suggested changes. The NOP under AMS is primarily a user-fee-based Federal program. Section 2107(a)(10) of the Organic Food Production Act of 1990 (OFPA) requires that the NOP provide for the collection of reasonable fees from producers, certifying agents, and handlers who participate in activities to certify, produce, or handle agricultural products as organically produced. Therefore, under the

statutory authority of OFPA, it is outside of the scope of the NOP to provide for the subsidization of producers, handlers, and certifying agents as desired by some commenters. We have, however, established provisions in this part that we believe will minimize the economic impact of the NOP on producers, handlers, and certifying agents.

(2) *Small Farmer Exemption Versus Lower Certification Fees.* Many commenters suggested that certification fees be lowered or based on a sliding scale rather than instituting an exemption from certification for small farmers and handlers.

We have not accepted the commenters' suggestion. We cannot remove the small farmer exemption because section 2106(d) of the Act requires that small farmers be provided an exemption from organic certification if they sell no more than $5,000 annually in value of agricultural products. Also, certification fees cannot be lowered by USDA because NOP under AMS is primarily a user-fee-based Federal agency. It is not our goal or objective to make a profit on our accreditation activities. However, our fees associated with the accreditation process are targeted toward recovering costs incurred during the accreditation process. Commenters expressed a concern that the accreditation fees charged by USDA would have an impact on the certification fees prescribed by certifying agents to operations seeking organic certification. We understand the commenters' concern that accreditation fees charged to certifying agents will most likely be calculated into the fees that certifiers charge their clients. However, we believe that our provision to waive the hourly service charges for accreditation during the first 18 months of implementation of the NOP should help reduce accreditation costs of the certifying agent and should, therefore, result lower certification fee charged by certifying agents. As provided by the Act and the regulations in this part, fees charged by certifying agents must be reasonable. Also, certifying agents must submit their fee schedule to the Administrator and may only charge those fees and charges filed with the Administrator. In addition, certifiers are required to provide their approved fee schedules to applicants for certification. Therefore, applicants for certification will be able to base their selection of a certifying agent on price if they choose. Moreover, there are no provisions in the regulations that preclude certifying agents from pricing their services on a sliding scale, as long as their fees are consistent and nondiscriminatory and are approved during the accreditation process.

(3) *Accreditation Fees.* Many industry commenters suggested that we reevaluate our accreditation fee structure. They believe the hourly accreditation rate proposed is unacceptable. Commenters were concerned that high accreditation costs would lead to high certification costs, which would have a greater impact on small operations. Some industry commenters also noted that we should be required to provide a fee schedule such as the certifiers are required to do. They stated that unless USDA provided a fee schedule that included travel costs, they would not be able to accurately budget for these costs. A few commenters wanted USDA to forgo charging travel costs or not charge travel time at the full rate. Several commenters also stated that the hourly rate stated in the proposal is much higher than what the people who actually perform the accreditations will earn. However, a large majority of the commenters favored the 18-month period in which AMS will not charge the hourly accreditation rate to applicants.

As stated in the proposal, the hourly rate will be the same as that of AMS' Quality Systems Certification Program. Due to the fact that AMS' Quality Systems Certification Program publishes one rate that is readily available to the public, it is our belief that it is unnecessary for the NOP to set up a separate fee schedule. The NOP will notify accredited certifying agents and applicants for accreditation of any proposed rate changes and final actions on such rates by AMS. We will also periodically report the status of fees to the National Organic Standards Board.

Those applicants and certifying agents who need accreditation cost estimates, including travel, for budgetary or other reasons may notify the NOP. The NOP staff will provide the applicant with a cost estimate, based on information provided by the applicant. As stated in an earlier response ((2)—Changes Requested But Not Made), the objective of the fee that is charged to accredit certifying agents is not to gain a profit for accreditation activities but to recover costs incurred during the accreditation process. As such, these costs include but are not limited to salaries, benefits, clerical help, equipment, supplies, etc.

Compliance

This portion of subpart G sets forth the enforcement procedures for the National Organic Program (NOP). These procedures describe the compliance responsibilities of the NOP Program Manager, State organic programs' (SOP) governing State officials, and State and private certifying agents. These provisions also address the rights of certified production and handling operations and accredited certifying agents operating under the NOP. The granting and denial of certification and accreditation are addressed under subparts E and F.

Description of Regulations

The Secretary is required under the Act to review the operations of SOP's, accredited certifying agents, and certified production or handling operations for compliance with the Act and these regulations. The Program Manager of the NOP may carry out compliance proceedings and provide oversight of compliance proceedings on behalf of the Secretary and the Administrator. The Program Manager will initiate proceedings to suspend or revoke a certified operation's certification if a certifying agent or SOP's governing State official fails to take appropriate enforcement action. The Program Manager may also initiate proceedings to suspend or revoke a certified operation's certification if the operation is found to have been erroneously certified by a certifying agent whose accreditation has been suspended or revoked. We anticipate, however, that most investigations, reviews, and analyses of certification noncompliance and initiation of suspension or revocation will be conducted by the certified operation's certifying agent. With regard to certifying agents, the Program Manager will, when appropriate, initiate proceedings to suspend or revoke the accreditation of a certifying agent for noncompliance with the Act and these regulations.

In States with an approved SOP, the SOP's governing State official is responsible for administering a compliance program for enforcement of the NOP/SOP. SOP's governing State officials may review and investigate complaints of noncompliance involving organic production or handling operations operating within their State and, when appropriate, initiate suspension or revocation of certification. SOP's governing State officials may also review and investigate complaints of noncompliance involving accredited certifying agents operating within their State. They must report the findings of any review and investigation of a certifying agent to the Program Manager along with any recommendations for appropriate action.

The compliance provisions of the NOP are consistent with the

requirements of the Administrative Procedure Act (APA) (5 U.S.C. 553–559) in that this program provides for due process including an opportunity for hearing, appeal procedures, written notifications of noncompliance, and opportunities to demonstrate or achieve compliance before any suspension or revocation of organic certification or accreditation is invoked. A compliance action regarding certification carried out under an approved SOP's compliance procedures will have the same force and effect as a certification compliance action carried out under these NOP compliance procedures. The notification process for denying certification and accreditation is laid out in subparts E and F, respectively.

Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued under these regulations must be sent to the recipient's place of business via a delivery service which provides return receipts. Certified operations and certifying agents must respond to all compliance notifications via a delivery service which provides return receipts.

Noncompliance Procedure for Certified Operations

The Act provides for the enforcement of certification requirements. Statutory oversight of production and handling operations by certifying agents includes review of organic plans, on-site inspections, residue and tissue testing, authority to conduct investigations and initiate suspension or revocation actions, and responsibility to report violations.

Notification of Noncompliance

A written notification of noncompliance will be sent to the certified operation when an inspection, review, or investigation reveals any noncompliance with the Act or these regulations. A noncompliance notification may encompass the entire operation or a portion of the operation. For instance, a violation at one farm may not warrant loss of certification at other farms of the certified operation not affected by the violation. The notification of noncompliance will provide: (1) A description of each condition, action, or item of noncompliance; (2) the facts upon which the notification is based; and (3) the date by which the certified operation must rebut the notification or correct the noncompliance and submit supporting documentation of the correction. A certified operation may continue to sell its product as organic upon receiving a notification of noncompliance and throughout the compliance proceeding and any appeal procedure which might follow the compliance proceeding unless otherwise notified by a State or Federal government agency.

If a certified operation believes the notification of noncompliance is incorrect or not well-founded, the certified operation may submit a rebuttal to the certifying agent or SOP's governing State official, as applicable, providing supporting data to refute the facts stated in the notification. The opportunity for rebuttal is provided to allow certifying agents and certified operations to informally resolve noncompliance issues. The rebuttal process should be helpful in resolving differences which may be the result of misinterpretation of requirements, misunderstandings, or incomplete information. Alternatively, the certified operation may correct the identified noncompliances and submit proof of such corrections. When the certified operation demonstrates that each noncompliance has been corrected or otherwise resolved, the certifying agent or SOP's governing State official, as applicable, will send the certified operation a written notification of noncompliance resolution.

Proposed Suspension or Revocation of Certification

If the noncompliance is not resolved or is not in the process of being resolved by the date specified in the notification of noncompliance, the certifying agent or SOP's governing State official will send the certified operation a written notification of proposed suspension or revocation of certification for the entire operation or a portion of the operation affected by the noncompliance. The notification will state: (1) The reasons for the proposed suspension or revocation; (2) the proposed effective date of the suspension or revocation; (3) the impact of the suspension or revocation on the certified operation's future eligibility for certification; and (4) that the certified operation has a right to request mediation or to file an appeal. The impact of a proposed suspension or revocation may include the suspension or revocation period or whether the suspension or revocation applies to the entire operation or to a portion or portions of the operation.

If a certifying agent or SOP's governing State official determines that correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification of proposed suspension or revocation. The certified operation will have an opportunity to appeal the proposed suspension or revocation.

If a certifying agent or SOP's governing State official has reason to believe that a certified operation has willfully violated the Act or regulations, a notification of proposed suspension or revocation will be sent to the certified operation. The proposed suspension or revocation will be for the entire operation or a portion of the operation. This notification, because it involves a willful violation, will be sent without first issuing a notification of noncompliance.

Mediation

A production or handling operation may request mediation of any dispute regarding denial of certification or proposed suspension or revocation of certification. Mediation is not required prior to filing an appeal but is offered as an option which may resolve the dispute more quickly than the next step, which is filing an appeal. When mediation is requested, it must be requested in writing to the applicable certifying agent. The certifying agent will have the option of accepting or rejecting the request for mediation. If the certifying agent rejects the request for mediation, the certifying agent must provide written notification to the applicant for certification or certified operation. The written notification must advise the applicant for certification or certified operation of the right to request an appeal in accordance with section 205.681. Any such appeal must be requested within 30 days of the date of the written notification of rejection of the request for mediation. If mediation is accepted by the certifying agent, such mediation must be conducted by a qualified mediator mutually agreed upon by the parties to the mediation. If an SOP is in effect, the mediation procedures established in the SOP, as approved by the Secretary, must be followed. The parties to the mediation will have no more than 30 days to reach an agreement following a mediation session. If mediation is unsuccessful, the production or handling operation will have 30 days from termination of mediation to appeal the denial of certification or proposed suspension or revocation in accordance with the appeal procedures in section 205.681.

Any agreement reached during or as a result of the mediation process must be in compliance with the Act and these regulations. The Secretary reserves the right to review any mediated agreement for conformity to the Act and these regulations and to reject any agreement

or provision not in conformance with the Act or these regulations

Suspension or Revocation

The certifying agent or SOP's governing State official will suspend or revoke the certified operation's certification when the operation fails to resolve the issue through rebuttal or mediation, fails to complete needed corrections, or does not file an appeal. The operation will be notified of the suspension or revocation by written notification. The certifying agent or SOP's governing State official must not send a notification of suspension or revocation to a certified operation that has requested mediation or filed an appeal while final resolution of either is pending.

The decision to suspend or revoke certification will be based on the seriousness of the noncompliance. Such decisions must be made on a case-by-case basis. Section 6519 of the Act establishes that willful violations include making a false statement, knowingly affixing a false label, or otherwise violating the purposes of the Act.

In addition to suspension or revocation, a certified operation that knowingly sells or labels a product as organic, except in accordance with the Act, will be subject to a civil penalty of not more than $10,000 per violation. Further, a certified operation that makes a false statement under the Act to the Secretary, an SOP's governing State official, or a certifying agent will be subject to the provisions of section 1001 of title 18, United States Code.

A certified operation whose certification has been suspended under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the NOP.

A certified operation or a person responsibly connected with an operation that has had its certification revoked will be ineligible to receive certification for an operation in which such operation or person has an interest for 5 years following the date of revocation. Accordingly, an operation will be ineligible for organic certification if one of its responsibly connected parties, was a responsibly connected party of an operation that had its certification revoked. The Secretary may, when in the best interest of the certification program, reduce or eliminate the period of ineligibility.

Noncompliance Procedure for Certifying Agents

The Program Manager, on behalf of the Secretary, may initiate a compliance action against an accredited certifying agent who violates the Act or these regulations. Compliance proceedings may be initiated as a result of annual reviews for continuation of accreditation, site evaluations, or investigations initiated in response to complaints of noncompliant activities. Compliance proceedings also may be initiated on recommendation of an SOP's governing State official.

A written notification of noncompliance will be sent by the Program Manager to an accredited certifying agent when an inspection, review, or investigation of such person reveals any noncompliance with the Act or these regulations. A notification of noncompliance will provide a description of each noncompliance found and the facts upon which the notification is based. Additionally, the notification will provide the date by which the certifying agent must rebut or correct each noncompliance described and submit supporting documentation of each correction.

When documentation received by the Program Manager demonstrates that each noncompliance has been resolved, the Program Manager will send the certifying agent a written notification of noncompliance resolution.

If a noncompliance is not resolved by rebuttal or correction, the Program Manager will issue a notification of proposed suspension or revocation of accreditation. The notification will state whether the suspension or revocation will be for the certifying agent's entire accreditation, that portion of the accreditation applicable to a particular field office, or a specific area of accreditation. For instance, if a certifying agent with field offices in different geographic areas is cited for a compliance violation at one field office, the Program Manager could determine that only that portion of the accreditation applicable to the noncompliant field office should be suspended or revoked.

If the Program Manager determines that the noncompliance cannot be immediately or easily corrected, the Program Manager may combine the notification of noncompliance and the proposed suspension or revocation in one notification.

The notification of proposed suspension or revocation of accreditation will state the reasons and effective date for the proposed suspension or revocation. Such notification will also state the impact of a suspension or revocation on future eligibility for accreditation and the certifying agent's right to file an appeal.

If the Program Manager has reason to believe that a certifying agent has willfully violated the Act or regulations, the Program Manager will issue a notification of proposed suspension or revocation of accreditation. The proposed suspension or revocation may be for the certifying agent's entire accreditation, that portion of the accreditation applicable to a particular field office, or a specified area of accreditation. This notification, because it involves a willful violation, will be sent without first issuing a notification of noncompliance.

The certifying agent may file an appeal of the Program Manager's determination pursuant to section 205.681. If the certifying agent fails to file an appeal of the proposed suspension or revocation, the Program Manager will suspend or revoke the certifying agent's accreditation. The certifying agent will be notified of the suspension or revocation by written notification.

A certifying agent whose accreditation is suspended or revoked must cease all certification activities in each area of accreditation and in each State for which its accreditation is suspended or revoked. Any certifying agent whose accreditation has been suspended or revoked must transfer to the Secretary all records concerning its certification activities that were suspended or revoked. The certifying agent must also make such records available to any applicable SOP's governing State official. The records will be used to determine whether operations certified by the certifying agent may retain their organic certification.

A certifying agent whose accreditation is suspended by the Secretary may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its accreditation. Such request must be accompanied by evidence demonstrating correction of each noncompliance and actions taken to comply with and remain in compliance with the Act and regulations. A certifying agent whose accreditation is revoked by the Secretary will be ineligible to be accredited as a certifying agent under the Act and regulations for a period of not less than 3 years following the date of revocation.

State Organic Programs' Compliance Procedures

An SOP's governing State official may initiate noncompliance proceedings against certified organic operations operating in the State. Such proceedings may be initiated for failure of a certified operation to meet the production or handling requirements of this part or the State's more restrictive requirements, as approved by the Secretary.

The SOP's governing State official must promptly notify the Program Manager of commencement of noncompliance proceedings initiated against certified operations and forward to the Program Manager a copy of each notice issued. A noncompliance proceeding, brought by an SOP's governing State official against a certified operation may be appealed in accordance with the appeal procedures of the SOP. There will be no subsequent rights of appeal to the Secretary. Final decisions of a State may be appealed to the United States District Court for the district in which such certified operation is located.

An SOP's governing State official may review and investigate complaints of noncompliance with the Act or regulations concerning accreditation of certifying agents operating in the State. When such review or investigation reveals any noncompliance, the SOP's governing State official must send a written report of noncompliance to the Program Manager. The SOP's governing State official's report must provide a description of each noncompliance and the facts upon which the noncompliance is based.

Compliance—Changes Based On Comments

This portion of subpart G differs from the proposal in several respects as follows:

(1) *Written Notifications.* We have added a new paragraph (d) to section 205.660. The preamble to the proposed rule stated that all written notifications sent by certifying agents and SOP's governing State officials, as well as rebuttals, requests for mediation, and notices of correction of noncompliances sent by certified operations, will be sent to the addressee's place of business by a delivery service which provides dated return receipts. The assurance of completed communications and timely compliance procedures was given as the reason for delivery by a service which provides dated return receipts. The addition of paragraph (d) at section 205.660 is one of the actions that we have taken in response to requests from commenters that we further clarify the compliance process. Paragraph (d) requires that each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued in accordance with sections 205.662, 205.663, and 205.665 and each response to such notification must be sent to the recipient's place of business via a delivery service which provides return receipts. This action will facilitate the effective administration of the compliance process by assuring a verifiable time line on the issuance and receipt of compliance documents and the response given to each such document.

(2) *Determination of Willful.* The preamble statement that ''only the Program Manager or governing State official may make the final determination that a violation is willful'' was incorrect and inconsistent with the regulatory language in section 205.662(d). Section 205.662(d) provides that, ''if a certifying agent or State organic program's governing State official has reason to believe that a certified operation has willfully violated the Act or regulations in this part, the certifying agent or State organic program's governing State official shall send the certified operation a notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance.'' Accordingly, as recommended by a commenter, the incorrect statement has been deleted from the preamble to this final rule.

(3) *Proposed Suspension or Revocation.* We have amended sections 205.662(c) and 205.665(c) by removing the redundant phrase ''or is not adequate to demonstrate that each noncompliance has been corrected'' from the first sentence of each section.

(4) *Suspension or Revocation.* We have amended section 205.662(e)(2) by adding ''while final resolution of either is pending'' to the end thereof. The language of section 205.662(e)(2) now reads: ''A certifying agent or State organic program's governing State official must not send a notification of suspension or revocation to a certified operation that has requested mediation pursuant to section 205.663 or filed an appeal pursuant to section 205.681 while final resolution of either is pending.'' We have made this change because we agree with those commenters who expressed the belief that section 205.662(e)(2) needed to be amended to clarify the duration of the stay on the issuance of a notification of suspension or revocation when mediation is requested or an appeal is filed. Several commenters stated that section 205.662(e)(2) needed to be amended to clarify that requesting mediation or filing an appeal does not indefinitely stop the suspension or revocation process.

(5) *Eligibility After Suspension or Revocation of Certification.* We have amended section 205.662(f) such that it now parallels section 205.665(g) which addresses suspension and revocation of certifying agents. We have also changed the title of section 205.662(f) from ''Ineligibility'' to ''Eligibility'' to parallel section 205.665(g). A few commenters referred to the provisions in section 205.665(g), which addresses eligibility after suspension or revocation of accreditation, and requested clarification of the difference between suspension and revocation of certification. Upon reviewing section 205.662(f), we decided that amendment was needed to clarify the difference between suspension and revocation of certification relative to eligibility for certification. Accordingly, we added a new paragraph (1) which provides that a certified operation whose certification has been suspended under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The paragraph also provides that the request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. We also amended what is now paragraph (2) of section 205.662(f) to clarify that the period of ineligibility following revocation of certification is 5 years unless reduced or eliminated by the Secretary.

Further, we have amended section 205.665(g)(1) to clarify that a certifying agent that has had its accreditation suspended may request reinstatement of its accreditation rather than submit a new request for accreditation. The amendment also clarifies that the reinstatement may be requested at any time unless otherwise stated in the notification of suspension. This amendment makes section 205.665(g)(1) similar to new paragraph (1) of section 205.662(f). This amendment is also consistent with commenter desires that the noncompliance procedures for certified operations and accredited certifying agents be similar.

(6) *Penalties for Violations of the Act.* We have amended section 205.662 by adding a new paragraph (g) which incorporates therein the provisions of

paragraphs (a) and (b) of section 2120, 7 U.S.C. 6519, Violations of Title, of the Act. Specifically, paragraph (g) provides that, in addition to suspension or revocation, any certified operation that knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than $10,000 per violation. This paragraph also provides that any certified operation that makes a false statement under the Act to the Secretary, an SOP's governing State official, or a certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code. Commenters requested regulatory language citing section 2120, 7 USC 6519, Violations of Title, of the Act. Commenters also requested a clearer description of enforcement. Specifically, they want provisions describing how USDA will deal with operations that make false claims or do not meet the NOP requirements. Further, numerous commenters expressed concern that there are no penalties in the regulations other than suspension and revocation. The European Community stated that it did not find, in the proposal, requirements for penalties to be applied by certifying agents when irregularities or infringements are found. The European Community went on to say that the European Union requires such penalties.

The Act provides for suspension and revocation of certification and the civil and criminal penalties addressed in 7 U.S.C. 6519. Certified operations are also required through the compliance program set forth in these regulations, to correct all noncompliances with the Act or regulations as a condition of retaining their certification. Furthermore, to get a suspended certification reinstated, an operation must submit a request to the Secretary. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. An operation or a person responsibly connected with an operation whose certification has been revoked will be ineligible to receive certification for a period of not more than 5 years.

We believe adding paragraph (g) will help clarify that there are penalties which may be imposed on certified operations that violate the Act and these regulations in addition to suspension or revocation.

The provisions of the Act and these regulations apply to all persons who sell, label, or represent their agricultural product as organic. Accordingly, persons who falsely sell, label, or represent their product as organic, are subject to the provisions of paragraphs (a) and (b) of section 2120, 7 USC 6519, of the Act. To clarify this, we have added a new paragraph (c) to section 205.100 of the Applicability subpart.

Certifying agents, SOP's governing State officials, and USDA will receive complaints alleging violations of the Act or these regulations. Certifying agents will review all complaints that they receive to determine if the complaint involves one of their clients. If the complaint involves a client of the certifying agent, the agent will handle the complaint in accordance with its procedures for reviewing and investigating certified operation compliance. If the complaint involves a person who is not a client of the certifying agent, the certifying agent will refer the complaint to the SOP's governing State official, when applicable, or, in the absence of an applicable SOP's governing State official, the Administrator. SOP's governing State officials will review all complaints that they receive in accordance with their procedures for reviewing and investigating alleged violations of the NOP and SOP. The SOP's governing State official's review of the complaint could result in referral of the complaint to a certifying agent when the complaint involves a client of the certifying agent, dismissal, or investigation by the SOP's governing State official. SOP's governing State officials will, as appropriate, investigate allegations of violations of the Act by noncertified operations operating within their State. USDA will review all complaints that it receives in accordance with its procedures for reviewing and investigating alleged violations of the NOP. USDA will refer complaints alleging violations of the NOP/SOP to the applicable SOP's governing State official, who may, in turn, refer the complaint to the applicable certifying agent. In States without an approved SOP, USDA will refer complaints to the applicable certifying agent. USDA will, as appropriate, investigate allegations of violations of the Act by noncertified operations operating in States where there is no approved SOP.

(7) *Mediation.* We have amended section 205.663 by providing that a dispute with respect to proposed suspension or revocation of certification may, rather than shall, be mediated. We have also provided that mediation must be requested in writing to the applicable certifying agent. The certifying agent will have the option of accepting or rejecting the request for mediation. If the certifying agent rejects the request for mediation, the certifying agent must provide written notification to the applicant for certification or certified operation. The written notification must advise the applicant for certification or certified operation of the right to request an appeal within 30 days of the date of the written notification of rejection of the request for mediation. If mediation is accepted by the certifying agent, such mediation must be conducted by a qualified mediator mutually agreed upon by the parties to the mediation.

Several commenters wanted section 205.663 amended to provide that disputes ''may,'' rather than ''shall,'' be mediated. The commenters advocated allowing the certifying agent to determine when mediation is a productive option. Several State commenters wanted to amend the second sentence to read as follows: ''If a State organic program is in effect, the mediation procedures established in the State organic program, as approved by the Secretary, will be followed for cases involving the State organic program and its applicants or certified parties.'' Another commenter wanted to retain the requirement that disputes ''shall'' be mediated but wanted disputes mediated in accordance with 7 CFR part 11 and section 205.681 of these regulations.

We concur that certifying agents should be authorized to reject a request for mediation, especially when they believe that the noncompliance issue is not conducive to mediation. Accordingly, we amended section 205.663 as noted above. We disagree, however, with the State commenters who want to amend the second sentence. We believe that the recommended change would exclude the clients of private-sector certifying agents operating within the State. USDA approval of an SOP will require that all certified operations operating within the State have the same opportunities for mediation, regardless of whether they are certified by a private or State certifying agent. If an approved SOP provides for mediation, such mediation must be available to all certified operations operating within the State. We also disagree with the commenter who requested that disputes be mediated in accordance with 7 CFR part 11 and section 205.681 of these regulations. First, we believe that States with an approved SOP must be allowed to establish their own mediation program and procedures. Second, the Act and its implementing regulations are subject to the APA for adjudication. The provisions of the APA generally applicable to agency adjudication are not applicable to proceedings under 7

CFR part 11, National Appeals Division Rules of Procedure. Even if 7 CFR part 11 were applicable, it does not address mediation procedures. Mediation is merely addressed in 7 CFR Part 11 as an available dispute resolution method along with its impact on the filing of an appeal.

(8) *Noncompliance Procedure for Certifying Agents.* We have amended section 205.665(a)(3) to clarify that, like certified operations, certifying agents must submit supporting documentation of each correction of a noncompliance identified in a notification of noncompliance. This amendment to section 205.665(a)(3) was made in response to commenter concerns that the noncompliance procedures for certified operations and certifying agents be similar. It had been our intent that certifying agents would have to document their correction of noncompliances and that the noncompliance procedures for certified operations and certifying agents would be similar.

Compliance—Changes Requested But Not Made

This subpart retains from the proposed rule, regulations on which we received comments as follows:

(1) *Funding for Enforcement.* Several commenters stated that USDA should provide funding to the States for the cost of performing enforcement activities. Others asked who should fund investigations and enforcement actions if certifying agents (State and private) are enforcing compliance with a Federal law. Numerous commenters requested information on how enforcement will be funded. The National Organic Standards Board (NOSB) recommended that the NOP examine existing models for capturing enforcement fees such as the State of California's registration program for all growers, handlers, and processors who use the word, ''organic,'' in marketing their products.

We disagree with the commenters who stated that USDA should fund enforcement activities (State and private). Costs for compliance under the NOP will be borne by USDA, States with approved SOP's, and accredited certifying agents. Each of the entities will bear the cost of their own enforcement activities under the NOP. AMS anticipates that States will consider the cost of enforcing their SOP's prior to seeking USDA approval of such programs. We also anticipate that certifying agents will factor the cost of compliance into their certification fee schedules.

We agree that there may be alternatives, such as the State of California's registration program, available to raise funds for enforcing the NOP. We will help identify existing models and potential options that may be available in the future at the Federal, State, or certifying agent level. In the interim, we believe that SOP's should explore funding options at their level and that certifying agents should factor the cost of enforcement into their certification fees structure.

(2) *Stop Sale.* A number of commenters requested that the regulations include the ability to stop sales or recall misbranded or fraudulently produced products. The Act does not authorize the NOP to stop sales or recall misbranded or fraudulently produced product. Accordingly, USDA cannot authorize stop sales or the recall of product. We also believe that the certified operation's right to due process precludes a stop sale or recall prior to full adjudication of the alleged noncompliance. However, the Food and Drug Administration (FDA) and the USDA's Food Safety Inspection Service (FSIS) have stop sale authority that may be used in certain organic noncompliance cases. Further, States may, at their discretion, be able to provide for stop sale or recall of misbranded or fraudulently produced products produced within their State. While the Act does not provide for stop sale or recall, it does provide at 7 U.S.C. 6519 that any person who: (1) knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than $10,000 and (2) makes a false statement under the Act to the Secretary, an SOP's governing State official, or a certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.

(3) *Notification of Proposed Suspension or Revocation.* A commenter recommended replacing ''notification of proposed suspension or revocation'' in section 205.662(d) with ''notification of suspension or revocation.'' Certification cannot be suspended or revoked without due process. Accordingly, the issuance of a written notification of proposed suspension or revocation is necessary to provide the certified operation with information regarding the alleged noncompliance(s) and its right to answer the allegations. For this reason we have not accepted the commenter's recommendation.

(4) *Mediation for Certifying Agents.* Several commenters recommended amending section 205.665(c)(4) to provide for mediation between a certifying agent and the Program Manager when a proposed suspension or revocation is disputed by the certifying agent. We have not accepted the recommendation. USDA uses 7 CFR part 1, Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes, for adjudicatory proceedings involving the denial, suspension, and revocation of accreditation.

(5) *Revocation of Accreditation.* A commenter stated that revocation of accreditation for 3 years is excessive. The commenter stated that a period of 6 to 12 months might be reasonable. We have not amended section 205.665(g)(2) because the Act requires that the period of revocation for certifying agents, who violate the Act and these regulations, be for not less than 3 years. Suspension is available to the Secretary to address less egregious noncompliances. A certifying agent whose accreditation is suspended may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its accreditation. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and these regulations.

(6) *Appeals Under SOP's.* Several commenters recommended amending 205.668(b) by adding at the end thereof: ''unless the State program's appeals procedures include judicial review through the State District Court.'' Another commenter wanted 205.668(b) amended by removing ''of the State organic certification program. There shall be no subsequent rights of appeal to the Secretary. Final decisions of a State may be appealed to the United States District Court for the district in which such certified operation is located,'' and inserting in its place ''at 7 CFR part 11 and 205.681 of this chapter.'' We have not accepted the recommendations because the Act at 7 U.S.C. 6520 provides that a final decision of the Secretary may be appealed to the United States District Court for the district in which the person is located. We consider an approved SOP to be the NOP for that State. As such, we consider the SOP's governing State official of such approved SOP to be the equivalent of a representative of the Secretary for the purposes of the appeals procedures under the NOP. Accordingly, the final decision of the SOP's governing State official of an approved SOP is considered the final decision of the Secretary and, as such, is appealable to

the United States District Court for the district in which the person is located, not a State's District Court.

We also disagree with the commenter who wanted all appeals to be made to the National Appeals Division under the provisions at 7 CFR part 11 and section 205.681 of these regulations. First, we believe that States with an approved SOP must be allowed to establish their own appeal procedures. Such procedures would have to comply with the Act, be equivalent to the procedures of USDA, and be approved by the Secretary. Second, as noted elsewhere in this preamble, the Act and its implementing regulations are subject to the APA for adjudication. The provisions of the APA generally applicable to agency adjudication are not applicable to proceedings under 7 CFR part 11.

Compliance—Clarifications

Clarification is given on the following issues raised by commenters:

(1) *Complaints, Investigations, Stop Sales, and Penalties.* Many commenters wanted USDA to spell out the responsibilities and authorities of States, State and private certifying agents, Federal agencies, and citizens to make complaints, investigate violations, halt the sale of products, and impose penalties. Anyone may file a complaint, with USDA, an SOP's governing State official, or certifying agent, alleging violation of the Act or these regulations. Certifying agents, SOP's governing State officials, and USDA will receive, review, and investigate complaints alleging violations of the Act or these regulations as described in item 6 above under Changes Based on Comments. Citizens have no authority under the NOP to investigate complaints alleging violation of the Act or these regulations.

As noted elsewhere in this preamble, the Act does not authorize USDA to stop the sale of product. Accordingly, USDA cannot authorize stop sales by accredited certifying agents. We also believe that the certified operation's right to due process precludes a stop sale prior to full adjudication of the alleged noncompliance. However, FDA and FSIS have stop sale authority that may be used in the event of food safety concerns. Further, States may, at their discretion, be able to provide for stop sale of product produced within their State. Citizens have no authority under the NOP to stop the sale of a product.

The Act and these regulations provide for suspension or revocation of certification by certifying agents, SOP's governing State officials, and the Secretary. Only USDA may suspend or revoke a certifying agent's accreditation. All proposals to suspend or revoke a certification or accreditation are subject to appeal as provided in section 205.681. The Act provides at 7 U.S.C. 6519 that any person who: (1) knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than $10,000; and (2) makes a false statement under the Act to the Secretary, an SOP's governing State official, or a certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code. Only USDA may bring an action under 7 U.S.C. 6519.

(2) *Certifying Agent's Identifying Mark.* The NOSB reaffirmed its recommendation which would allow private certifying agents to prevent the use of their service mark (seal) upon written notification that: (1) certification by the private certifying agent has been terminated, and (2) the certifying agent has 30 days to appeal the certifying agent's decision to the Secretary of Agriculture. We will neither prohibit nor approve a certifying agent's actions to withdraw a certified operation's authority to use the certifying agent's identifying mark for alleged violations of the Act or regulations. We stand fast in our position that all certified operations are to be given due process prior to the suspension or revocation of their certification. The reader is also reminded that the certifying agent cannot terminate, suspend, or revoke a certification if the certified operation files an appeal with an SOP's governing State official, when applicable, or the Administrator as provided for in the notification of proposed suspension or revocation. The certifying agent accepts full liability for any action brought as a result of the withdrawal of a certified operation's authority to use the certifying agent's identifying mark.

(3) *Loss of Certification.* A commenter posed several questions regarding the loss of certification. The commenter's questions and our responses are as follows.

How will consumers and affected regulatory agencies know if a grower or handler loses its certification? We will provide public notification of suspensions and revocations of certified operations through means such as the NOP website.

What will the effect of a lost certification be? Suspension or revocation of a producer's or handler's certification will require that the producer or handler immediately cease its sale, labeling, and representation of agricultural products as organically produced or handled as provided in the suspension or revocation order. A production or handling operation or a person responsibly connected with an operation whose certification has been suspended may at any time, unless otherwise stated in the notification of suspension, submit a new request for certification in accordance with section 205.401. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. An operation or a person responsibly connected with an operation whose certification has been revoked will be ineligible to receive certification for a period of not more than 5 years following the date of such revocation, as determined by the Secretary. Any producer or handler who sells, labels, or represents its product as organic contrary to the provisions of the suspension or revocation order would be subject to prosecution under 7 U.S.C. 6519 of the Act.

Will the certifying agent give a future effective date for loss of certification, or could the loss of certification be immediate or even retroactive? Suspension or revocation will become effective as specified in the suspension or revocation order once it becomes final and effective. The operation, upon suspension or revocation, will be prohibited from selling, labeling, and representing its product as organic per the provisions of the suspension or revocation order.

If organic products already on the market were grown or handled by someone whose certification is revoked or suspended, would USDA require that the products be recalled and relabeled? USDA will not, unless the noncompliance involves a food safety issue under FSIS, require the recall or relabeling of product in the channels of commerce prior to the issuance of a suspension or revocation order. First, at the time the product was produced, it may have been produced in compliance with the Act and these regulations. Second, USDA does not have the authority, under the Act, to issue a stop sale order for product sold, labeled, or represented as organic and placed in the channels of commerce prior to suspension or revocation of a certified operation's certification. The Act, however, provides at 7 U.S.C. 6519(a) for the prosecution of any person who knowingly sells or labels a product as organic, except in accordance with the Act. Such persons shall be subject to a civil penalty of not more than $10,000 per violation.

(4) *Investigations.* A commenter suggested that we amend section

205.661(a) to require that all complaints must be investigated in accordance with the certifying agent's complaints policy. The commenter also stated that the Administrator should know which complaints were not investigated. We disagree that all complaints must be investigated since, upon review of the alleged noncompliance, some complaints may lack grounds for investigation. For example, a concerned citizen could allege that an organic producer was seen applying a pesticide to a specific field. Upon review of the allegation, the certifying agent could determine that the producer in question was a split operation and that the field in question was part of the conventional side of the production operation. Accordingly, there would be no need for an investigation. However, the certifying agent will be expected to: (1) take each allegation seriously, (2) review each complaint received, (3) make a determination as to whether there may be a basis for conducting an investigation, (4) investigate all allegations when it is believed that there may be a basis for conducting the investigation, and (5) maintain a detailed log of all complaints received and their disposition. The actions taken by the certifying agent must be in conformance with the certifying agent's procedures for reviewing and investigating certified operation compliance.

(5) *Deadline for the Correction of a Noncompliance.* Several commenters requested that 205.662(a)(3) be amended by adding: ''The deadline for correction of the noncompliance may be extended at the discretion of the certifier if substantial progress has been made to correct the noncompliance.'' We believe that the requested amendment is unnecessary. Section 205.662(a)(3) requires that the notification of noncompliance include a date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each correction when correction is possible. There is no prohibition preventing the certifying agent from extending the deadline specified when the certifying agent believes that the certified operation has made a good faith effort at correcting each noncompliance.

(6) *Compliance with SOP.* Several States requested that section 205.665 be amended to clarify how States may handle a private certifying agent found to be in noncompliance with SOP's approved by the Secretary. A majority of these commenters also asked if NOP intends to suspend or revoke the accreditation of certifying agents on a State-by-State basis. Section 205.668(c) authorizes an SOP's governing State official to review and investigate complaints of noncompliance with the Act or regulations concerning accreditation of certifying agents operating in the State. When such review or investigation reveals any noncompliance, the SOP's governing State official shall send a written report of noncompliance to the NOP Program Manager. The report shall provide a description of each noncompliance and the facts upon which the noncompliance is based. The NOP Program Manager will then employ the noncompliance procedures for certifying agents as found in section 205.665. This may include additional investigative work by AMS. Only USDA may suspend or revoke a certifying agent's accreditation.

SOP's must meet the general requirements for organic programs specified in the Act and be at least equivalent to these regulations. Accordingly, noncompliances worthy of suspension or revocation would in all probability be worthy of national suspension or revocation of accreditation for one or more areas of accreditation. Therefore, USDA does not anticipate suspending or revoking accreditations, or areas of accreditation, on a State-by-State basis. It is possible, however, that the Secretary may decide to only suspend or revoke a certifying agent's accreditation or an area of accreditation to certify producers or handlers within a given State. Such a decision would in all probability be tied to a State's more restrictive requirements.

Inspection and Testing, Reporting, and Exclusion from Sale

This portion of subpart G sets forth the inspection and testing requirements for agricultural products that have been produced on organic production operations or handled through organic handling operations.

Residue testing plays an important role in organic certification by providing a means for monitoring compliance with the National Organic Program (NOP) and by discouraging the mislabeling of agricultural products. This testing program provides State organic programs' (SOP) governing State officials and certifying agents with a tool for ensuring compliance with three areas for testing: (1) preharvest residue testing, (2) postharvest residue testing, and (3) testing for unavoidable residual environmental contamination levels.

Description of Regulations

General Requirements

Under the residue testing requirements of the NOP, all agricultural products sold, labeled, or represented as organically produced must be available for inspection by the Administrator, SOP's governing State official, or certifying agent. Organic farms and handling operations must be made available for inspection under subpart E, Certification. In addition, products from the aforementioned organic operations may be required by the SOP's governing State official or certifying agent to undergo preharvest or postharvest testing when there is reason to believe that agricultural inputs used in organic agriculture production or agricultural products to be sold or labeled as organically produced have come into contact with prohibited substances or have been produced using excluded methods. The cost of such testing will be borne by the applicable certifying agent and is considered a cost of doing business. Accordingly, certifying agents should make provisions for the cost of preharvest or postharvest residue testing when structuring certification fees.

Preharvest and Postharvest Residue Testing

The main objectives of the residue testing program are to: (1) ensure that certified organic production and handling operations are in compliance with the requirements set forth in this final rule and (2) serve as a means for monitoring drift and unavoidable residue contamination of agricultural products to be sold or labeled as organically produced. Any detectable residues of a prohibited substance or a product produced using excluded methods found in or on samples during analysis will serve as a warning indicator to the certifying agent.

The Administrator, SOP's governing State official, or certifying agent may require preharvest or postharvest testing of any agricultural input used in organic agricultural production or any agricultural product to be sold or labeled as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients or food group(s)).'' It is based on the Administrator's, SOP's governing State official's, or certifying agent's belief that an agricultural product or agricultural input has come into contact with one or more prohibited substances or has been produced using excluded methods. Certifying agents do not have to conduct residue tests if they do not have reason to believe that there is a need for testing.

Certifying agents must ensure, however, that certified organic operations are operating in accordance with the Act and the regulations set forth in this part.

The ''reason to believe'' could be triggered by various situations, for example: (1) The applicable authority receiving a formal, written complaint regarding the practices of a certified organic operation; (2) an open container of a prohibited substance found on the premises of a certified organic operation; (3) the proximity of a certified organic operation to a potential source of drift; (4) suspected soil contamination by historically persistent substances; or (5) the product from a certified organic operation being unaffected when neighboring fields or crops are infested with pests. These situations do not represent all of the possible occurrences that would trigger an investigation. Preharvest or postharvest residue testing will occur on a case-by-case basis.

In each case, an inspector representing the Administrator, SOP's governing State official, or certifying agent or will conduct sampling. According to subpart F, Accreditation, private or State entities accredited as certifying agents under the NOP must ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise to successfully perform the duties assigned. Therefore, all inspectors employed by certifying agents to conduct sampling must have sufficient expertise in methods of chain-of-custody sampling. Moreover, testing for chemical residues must be performed in an accredited laboratory. When conducting chemical analyses, the laboratory must incorporate the analytical methods described in the most current edition of the *Official Methods of Analysis of the AOAC International* or other current applicable validated methodology for determining the presence of contaminants in agricultural products. Results of all analyses and tests performed under section 205.670 must be promptly provided to the Administrator, *except*, that, where an SOP exists, all test results and analyses should be provided to the SOP's governing State official by the applicable certifying party that requested testing. Residue test results and analyses must also be, according to section 205.403(e)(2), provided to the owner of the certified organic operation whose product was tested. All other parities desiring to obtain such information must request it from the applicable certifying agent.

OFPA requires certifying agents, to the extent of their awareness, to report violations of applicable laws relating to food safety to appropriate health agencies such as EPA and FDA. When residue testing indicates that an agricultural product contains pesticide residues or environmental contaminants that exceed either the EPA tolerance level or FDA action level, as applicable, the certifying agent must promptly report data revealing such information to the Federal agency whose regulatory tolerance or action level has been exceeded.

Residue Testing and Monitoring Tools

When testing indicates that an agricultural product to be sold or labeled as organically produced contains residues of prohibited substances, certifying agents will compare the level of detected residues with 5 percent of the Environmental Protection Agency (EPA) tolerance for the specific residue detected on the agricultural product intended to be sold as organically produced. This compliance measure, 5 percent of EPA tolerance for the detected prohibited residue, will serve as a standard for the Administrator, SOP's governing State officials, and certifying agents to assist in monitoring for illegal use violations.

In addition, we intend to establish levels of unavoidable residual environmental contamination (UREC) for crop-and site-specific agricultural commodities to be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with . . .'' These levels will represent limits at which USDA may take compliance action to suspend the use of a contaminated area for organic agricultural production. Currently, USDA is seeking scientifically sound principles and measures by which it can establish UREC levels to most effectively address issues of unavoidable residual environmental contamination with respect to this rule. However, in the interim, UREC will be defined as the Food and Drug Administration's (FDA) action levels for poisonous or deleterious substances in human food or animal feed. UREC levels will be initially set for persistent prohibited substances (aldrin, dieldrin, chlordane, DDE, etc.) in the environment. They may become more inclusive of prohibited residues as additional information becomes available. Unavoidable residual environmental contamination levels will be based on the unavoidability of the chemical substances and do not represent permissible levels of contamination where it is avoidable.

Analyses and test results will be available for public access unless the residue testing is part of an ongoing compliance investigation. Information relative to an ongoing compliance investigation will be confidential and restricted to the public.

Detection of Prohibited Substances or Products Derived from Excluded Methods

In the case of residue testing and the detection of prohibited substances in or on agricultural products to be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with . . .'' products with detectable residues of prohibited substances that exceed 5 percent of the EPA tolerance for the specific residue or UREC cannot be sold or labeled as organically produced. When such an agricultural crop is in violation of these requirements, the certification of that crop will be suspended for the period that the crop is in production. Certifying agents must follow the requirements specified in sections 205.662 and 205.663 of subpart G, Compliance.

The ''5 percent of EPA tolerance'' standard is considered a level above which an agricultural product cannot be sold as organic, regardless of how the product may have come into contact with a potential prohibited substance. This standard has been established to: (1) satisfy consumer expectations that organic agricultural products will contain minimal chemical residues and (2) respond to the organic industry's request to implement a standard comparable to current industry practices. However, the ''5 percent of EPA tolerance'' standard cannot be used to automatically qualify agricultural products as organically produced, even if the level of chemical residues detected on an agricultural product is below 5 percent of the EPA tolerance for the respective prohibited substance. This final rule is a comprehensive set of standards and regulations that determines whether a product can or cannot be considered to carry the specified organic labeling terms in subpart D, Labeling. Therefore, in addition to this section of subpart G, Administrative, all other requirements of this part must be met by certified organic operations to have an agricultural product considered ''organically produced.''

When residue testing detects the presence of *any* prohibited substance, whether above or below 5 percent of the EPA tolerance for the specific pesticide or UREC, the SOP's governing State official or certifying agent may conduct an investigation of the certified organic

operation to determine the cause of the prohibited substance or product in or on the agricultural product to be sold or labeled as organically produced. The same shall occur if testing detects a product produced using excluded methods. If the investigation reveals that the presence of the prohibited substance or product produced using excluded methods in or on an agricultural product intended to be sold as organically produced is the result of an intentional application of a prohibited substance or use of excluded methods, the certified organic operation shall be subject to suspension or revocation of its organic certification. In addition, any person who knowingly sells, labels, or represents an agricultural product as organically produced in violation of the Act or these regulations shall be subject to a civil penalty of not more than $10,000 per violation.

Emergency Pest or Disease Treatment Programs

When a prohibited substance is applied to an organic production or handling operation due to a Federal or State emergency pest or disease treatment program and the organic handling or production operation otherwise meets the requirements of this final rule, the certification status of the operation shall not be affected as a result of the application of the prohibited substance, except that: (1) Any harvested crop or plant part to be harvested that has contact with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program cannot be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with . . .'' and (2) any livestock that are treated with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program or product derived from such treated livestock cannot be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with . . .''

However, milk or milk products may be labeled or sold as organically produced beginning 12 months following the last date that the dairy animal was treated with the prohibited substance. Additionally, the offspring of gestating mammalian breeder stock treated with a prohibited substance may be considered organic if the breeder stock was not in the last third of gestation on the date that the breeder stock was treated with the prohibited substance.

Residue Testing—Changes Based on Comments

This portion of subpart G differs from our proposal in several respects as follows:

(1) *Reporting Requirements.* Commenters were not satisfied with the language in section 205.670(d)(1) that required results of all analyses and tests performed under section 205.670 to be provided to the Administrator promptly upon receipt. They asked that the paragraph be amended to include that: (1) Results of all analyses and tests performed under section 205.670 be provided by the Administrator to the appropriate SOP's governing State official; and (2) test results be made immediately available to the owner of the material sampled. They stated that since State organic certification programs are responsible for enforcement within their State, results of residue tests conducted by certifying agents must be provided to the SOP's governing State official for routine monitoring and for investigating possible violations of the Act.

We agree with the commenters and have responded to their concerns accordingly. To ensure that SOP's receive results of all tests and analyses conducted under the inspection and testing requirements of subpart G, section 205.670(d) has been amended to include that the results of all analyses and residue tests must be provided to the Administrator promptly upon receipt; Except: That where an SOP exists, all test results and analyses should be provided to the SOP's governing State official.

In regard to the commenters' request that certified organic operations be provided with a copy of test results from samples taken by an inspector, an additional paragraph, section 205.403(e)(2), has been added to subpart E, Certification, that assures that such information is provided to the owners of certified organic operations by the certifying agents.

(2) *Integrity Of Organic Samples.* We have modified language in section 205.670(c) to clarify our intent regarding the maintenance of sample integrity. The proposed rule stated that ''sample integrity must be maintained in transit, and residue testing must be performed in an accredited laboratory.'' During the final rulemaking process, we did not believe that our intent was clear on this subject. Our intent is to ensure that sample integrity is maintained throughout the entire chain of custody during the residue testing process. Proposed language only suggests that sample integrity be maintained in transit. Therefore, we have changed the second sentence in section 205.670(c) to state that ''sample integrity must be maintained throughout the chain of custody, and residue testing must be performed in an accredited laboratory.''

(3) *Reporting Residue and Other Food Safety Violations to Appropriate Health Agencies.* In the proposed rule, section 205.671(b) under Exclusion from Organic Sale states, ''If test results indicate a specific agricultural product contains pesticide residues or environmental contaminants that exceed the FDA's or the EPA's regulatory tolerances, the data must be reported promptly to the appropriate public health agencies.'' During the final rulemaking process, a group of commenters suggested that we move section 205.671(b) into section 205.670 as paragraph (e). They recommended that we move section 205.671(b) because it does not specifically address the sale of organically produced products, as indicated by the section heading. They recommended that section 205.671(b) be placed under section 205.670 as paragraph (e) because it dealt with the reporting of residues that exceed Federal regulatory tolerances. The commenters further stated that, while section 205.671(b) creates a duty to report, it is not specific as to who must report.

We have accepted the suggestions of the commenters and have responded accordingly. We have removed section 205.671(b) and relocated it under section 205.670 as paragraph (e). We have also modified the regulatory text of paragraph (e) to include language that instructs certifying agents to report, when residue testing indicates that an agricultural product contains pesticide residues or environmental contaminants that exceed either the EPA tolerance level or FDA action level, as applicable, data reveling such information to the Federal agency whose regulatory tolerance or action level has been exceeded.

(4) *Exclusion from Organic Sale.* We have reviewed section 205.671(a), removed the requirement to implement the Pesticide Data Program (pdp) estimated national mean as a compliance tool in monitoring for the presence of unacceptable levels of prohibited substances in agricultural products intended to be sold as organic, and added the ''5 percent of EPA tolerance'' standard.

Commenters voiced the opinion that the estimated national mean would be a difficult standard in organic agricultural production for several reasons. Some stated that the estimated national mean was a new concept that would confuse

producers and handlers because they would not know the exact definition of ''estimated national mean'' and how it would be determined. Others stated that the PDP was too limited in scope to employ an estimated national mean for all commodity/pesticide combinations. Commenters reasoned that PDP data were limited in terms of the agricultural commodities that are sampled and tested.

Another group of commenters stated that PDP data would be unfair to use in the NOP's residue testing plan. They argued PDP data should not be used to set maximum residue levels for organic agricultural products because PDP samples its products as close to the point of consumption as possible. As a result, commenters believe that PDP data may not be totally reflective of residue levels of agricultural products at the farmgate level. Since most residue testing in organic agricultural production takes place at the farmgate, these commenters argued that it would be an inappropriate standard for organic agricultural production.

As a result, a large number of commenters suggested that we reconsider using the estimated national mean as a standard for the maximum allowable residues on organically produced products. Instead, commenters recommended that the NOP incorporate the National Organic Standards Board's (NOSB) recommendation and current industry practice of using 5 percent of the EPA tolerance as a maximum level of pesticide residue on organic agricultural products. Commenters argued that using 5 percent of the EPA tolerance provides a sense of confidence to the consumers of organic agricultural products.

In many respects, we agree with the commenters. We have revisited using PDP data to establish an estimated national mean for commodity/pesticide combinations and for setting a maximum level of pesticide residue that could exclude agricultural products from being sold, labeled, or represented as organic. As a result, we have concluded that such an approach may be somewhat underdeveloped to incorporate into the NOP. We have reached this conclusion based on many of the same arguments presented by commenters (i.e., limited scope of agricultural products tested under PDP, product sampling based upon market availability, testing near the point of consumption, etc.). Also, we estimated that there would be a considerable time lag between the implementation of the NOP and defining a comprehensive list of estimated national means for all commodity/pesticide combinations. Thus, we have decided not to use the estimated national mean as a tool for monitoring organic agricultural products for the presence of prohibited substances and as a standard to exclude agricultural products from being sold, labeled, or represented as organically produced.

Instead, we have decided to follow the recommendation of the commenters by replacing the estimated national mean for specific commodity/pesticide pairs with 5 percent of the EPA tolerance for the specific pesticide. Therefore, when residue testing detects prohibited substances at levels that are greater than 5 percent of the EPA tolerance for the specific pesticide detected on the particular product samples, the agricultural product must not be sold or labeled as organically produced.

We fully understand that the EPA tolerance is defined as the maximum legal level of a pesticide residue in or on a raw or processed agricultural commodity. We also acknowledge that the EPA tolerance is a health-based standard. We are *not* trying to employ the 5 percent standard in a manner similar to that of EPA. As mentioned in our proposal, the national organic standards, including provisions governing prohibited substances, are based on the method of production, not the content of the product. The primary purpose of the residue testing approach described in this final rule, then, is to provide an additional tool for SOP's governing State officials and certifying agents to use in monitoring and ensuring compliance with the NOP.

(5) *Unavoidable Residual Environmental Contamination.* We have defined, as an interim measure, UREC as the FDA action levels for poisonous or deleterious substances in human food or animal feed.

Section 205.671 proposed the use of UREC to serve as a residue testing tool for compliance. Commenters believed UREC levels, as prescribed in section 205.671 of the proposed rule, would be problematic as a standard because they were undefined. Commenters argued that it would be impractical and very expensive to establish UREC levels for every organic crop and region in the United States. They suggested that UREC levels be managed as a practice standard or program manual issue. They also expressed the concern that inconsistent application of UREC levels could create difficulties for certifying agents and certified operations.

We agree that UREC levels should be defined. We are seeking scientifically sound principles and measures by which we can establish UREC levels to most effectively address issues of unavoidable residual contamination with respect to this rule. However, in the interim, the ability to implement an undefined standard would be difficult for certifying agents. Therefore, we have included language in the preamble that temporarily defines UREC as the FDA action levels for poisonous or deleterious substances in human food or animal feed. When residue testing detects the presence of a prohibited substance on an agricultural product greater than such levels mentioned, the agricultural product cannot be sold as organic. We have decided to use FDA action levels for UREC because they encompass many of the toxic, persistent chemicals and heavy metals that are present in the environment and may be found on food and animal feed. As mentioned earlier, the FDA action levels are being employed in this part as temporary measures for compliance. We will continue to seek scientifically sound principles and measures by which to establish UREC levels that more appropriately satisfy the purposes of this part.

Residue Testing—Changes Requested But Not Made

This subpart retains from the proposed rule regulations on which we received comments as follows:

(1) *Residue Testing Responsibility.* Commenters petitioned that we remove the requirement in section 205.670(b) that states residue tests must be conducted by the applicable SOP's governing State official or the certifying agent at the official's or certifying agent's own expense. The commenters expressed the opinion that we were practicing ''micromanagement.'' They also said that there was no need for the proposal to be so detailed with respect to who pays for residue testing. Based on the commenters' responses, residue analyses are reportedly paid by producers, buyers, brokers, certifiers, and government residue testing programs.

We have not adopted the suggestion of the commenters. In the proposal, we stated that conducting residue tests was considered a cost of doing business for certifying agents. Our position has not changed. Certifying agents can factor residue testing costs into certification fees. It is not our intention to ''micromanage'' the way that certifying agents conduct business. Section 2107(a)(6) of the Act requires that certifying agents conduct residue testing of agricultural products that have been produced on certified organic farms and handled through certified organic handling operations. OFPA also

requires, under section 2112(a) through (c), that certifying agents enforce its provisions by implementing a system of residue testing to test products sold or labeled as organically produced. In addition, subpart E, Certification, authorizes certifying agents to conduct on-site inspections, which may include residue testing, of certified organic operations to verify that the operation is complying with the provisions in the Act and the regulations in this part. Certifying agents are responsible for monitoring organic operations for the presence of prohibited substances; we view residue testing as a cost of doing business. Therefore, we believe that certifying agents should factor monitoring costs associated with implementing the provisions in the Act and Rule into their certification fees.

(2) *Reporting to Federal Regulatory Agencies.* Commenters disagree with section 205.671(b) of the proposed rule which states that if test results indicate a specific agricultural product contains pesticide residues or environmental contaminants that exceed the FDA action level or EPA tolerance, the data must be reported promptly to appropriate public health agencies. Commenters believe that since results of all analyses and tests must be provided to the Administrator, USDA should be responsible for communicating such test results to other Federal agencies such as FDA or EPA if regulatory tolerances or action levels are exceeded. They also suggested that section 205.671(b) be removed from the national regulations. Commenters expressed the view that such a requirement is not related to organic certification.

We do not agree with the commenters. It is not our intent to create additional responsibility for the certifying agent. Section 205.671(b), redesignated as section 205.670(e), is a statutory requirement. Section 2107(a)(6) of the Organic Food Production Act of 1990 requires certifying agents, to the extent of their awareness, to report violations of applicable laws relating to food safety to appropriate health agencies such as EPA and FDA. Therefore, due to section 2107 of the Act, section 205.670(e) has been included in the national regulations.

(3) *''Threshold'' for Genetic Contamination.* Many commenters suggested that we establish a ''threshold'' for the unintended or adventitious presence of products of excluded methods in organic products. Some commenters argued that a threshold is necessary because, without the mandatory labeling of biotechnology-derived products, organic operations and certifying agents could not be assured that products of excluded methods were not being used. Others argued that, without an established threshold, the regulations would constitute a ''zero tolerance'' for products of excluded methods, which would be impossible to achieve.

We do not believe there is sufficient consensus upon which to establish such a standard at this time. Much of the basic, baseline information about the prevalence of genetically engineered products in the conventional agricultural marketplace that would be necessary to set such a threshold—e.g., the effects of pollen drift where it may be a factor, the extent of mixing at various points throughout the marketing chain, the adventitious presence of genetically engineered seed in nonengineered seed lots—is still largely unknown. Our understanding of how the use of biotechnology in conventional agricultural production might affect organic crop production is even less well developed.

Also, as was pointed out in some comments, the testing methodology for the presence of products of excluded methods has not yet been fully validated. Testing methods for some biotechnology traits in some commodities are becoming commercially available. Without recognized methods of testing for and quantifying of all traits in a wide range of food products, however, it would be very difficult to establish a reliable numerical tolerance.

There are publicly and privately funded research projects underway that may provide useful baseline information. Efforts of Federal agencies to clarify the marketing and labeling of biotechnology- and nonbiotechnology-derived crops may also help address these concerns. FDA, for example, is developing guidance for food producers who voluntarily chose to label biotechnology- and nonbiotechnology-derived foods. USDA is also preparing a **Federal Register** Notice to seek public comment on the appropriate role, if any, that it can play in facilitating the marketing of agricultural products through the development of ''quality assurance'' type programs that help to preserve the identity of agricultural commodities. USDA, in cooperation with the technology providers, is also working to validate testing procedures and laboratories for some commodities.

All of these efforts may help to provide information on this issue. Practices for preserving product identity, including segregating genetically engineered and nongenetically engineered products, are evolving in some conventional markets. As we discussed in the preamble to the proposed rule, we anticipate that these evolving industry best practices and standards will become the standards for implementing the provisions in this regulation relating to the use of excluded methods. As was also discussed in the proposed rule, these regulations do not establish a ''zero tolerance'' standard. As with other substances not approve for use in organic production systems, a positive detection of a product of excluded methods would trigger an investigation by the certifying agent to determine if a violation of organic production or handling standards occurred. The presence of a detectable residue alone does not necessarily indicate use of a product of excluded methods that would constitute a violation of the standards.

(4) *Certification Status After Emergency Pest or Disease Treatment.* We have not modified language in section 205.672 that would affect the certification status of a certified organic operation if the operation had been subjected to a Federal or State emergency pest or disease treatment program.

Section 205.672 states that when a prohibited substance is applied to a certified operation due to a Federal or State emergency pest or disease treatment program and the certified operation otherwise meets the requirements of this part, the certification status of the operation shall not be affected as a result of the application of the prohibited substance: Provided, That, the certified operation adheres to certain requirements prescribed by the NOP. One group of commenters informed us that they did not support maintaining the organic status of an operation that has been directly treated with prohibited substances, regardless of the reason for treatment. They believe that Federal and State emergency pest or disease treatment programs should provide alternatives for organic operations whenever feasible. If no alternative measure is feasible, the organic operation should choose between voluntary surrender of their organic status on targeted parts of the operation or destruction of the crop to eliminate pest habitat. The commenters also suggested that compensation should be provided to organic producers whose crops must be destroyed to eliminate habitat. They feel that allowing the application of prohibited materials to certified organic land without affecting the certification status violates the trust consumers place in organic certification.

We disagree with the position of the commenters. Historically, residues from emergency pest or disease treatment programs have been treated as drift cases by certifiers. In these cases, the specific crop may not be sold as organic, but the organic status of future crop years are not affected. We intend to handle such cases in a similar manner. We understand that commenters would like us to remove the certification of an organic operation that has been treated with a prohibited substance, but organic certification is a production claim, not a content claim. We, along with the commenters, are concerned with consumers trusting organic certification. At the same time, we are concerned with the welfare of certified organic operations. We have tried to include language in section 205.672 that would address both issues. We believe that, if a certified organic grower has been a good steward of his/her land and has managed the production of his/her product(s) in accordance with all regulations in the Act and other requirements in this part, the certification status of the operation should not be affected. The application of a prohibited substance as part of a Federal or State emergency pest or disease treatment program is outside the control of the certified operation. We also believe that maintaining consumer trust is important. Thus, section 205.672 states that any harvested crop or plant part to be harvested that has been treated with a prohibited substance as part of a Federal or State emergency pest or disease treatment program cannot be sold as organically produced. Therefore, the certified organic operation can retain its certification status, and the consumer can be assured that a product from a certified organic operation that has been in contact with a prohibited substance as the result of a Federal or State pest or disease treatment program will not enter the organic marketplace. Accordingly, we have not made the change to section 205.672 as proposed by the commenters.

(5) *Emergency Pest or Disease Treatment Programs.* Commenters suggested that the Department add a new paragraph to section 205.672 that states ''the certifying agent must monitor production operations that have been subjected to a Federal or State emergency pest or disease treatment program, and may require testing of following crops, or an extended transition period for affected production sites, if residue test results indicate the presence of a prohibited substance.'' Commenters said the language in the proposed rule did not clearly establish that a transition period could be needed after contamination of a certified organic operation by a government-mandated spray program. They felt that there may be a need for a case-by-case determination by the certifying agent as to when it would be best for a certified organic operation to begin selling its products as organically produced after it has been subject to a government mandated spray program.

We understand that commenters would like USDA to mandate certifying agents to monitor operations that have been subject to Federal or State emergency pest or disease treatment programs; however, we do not see a need to prescribe such a provision. Based on the responsibilities of being a USDA-accredited certifier, it is our belief that certifying agents would monitor a certified organic operation that has been subjected to a Federal or State emergency pest or disease treatment program to make sure that product being produced for organic sale is actually being produced in accordance with the Act and the regulations in this part. Certifying agents have been granted the authority to conduct additional on-site inspections of certified organic operations to determine compliance with the Act and national standards under subpart E, section 205.403. Commenters requested that we include language that would allow certifying agents to recommend an extended transition period for affected production sites if residue tests indicate the presence of a prohibited substance. Again, we understand the commenters' concern, but we are not aware of comprehensive soil residue data that could guide certifying agents in determining appropriate withdrawal intervals for operations that have been subjected to emergency pest or disease treatment programs.

Residue Testing—Clarifications

Clarification is given on the following issues raised by commenters as follows:

(1) *Sampling and Testing.* Commenters stated that the purpose of residue testing under the Act is to assure that organically produced agricultural products that are sold as organic do not contain pesticide residues or residues of other prohibited substances that exceed levels as specified by the NOP. Based on language in section 205.670(b) of the proposed rule, commenters expressed the opinion that the Agricultural Marketing Service (AMS) was, not only requiring residue testing of organic agricultural products, but also of ''any'' agricultural input used or agricultural product intended to be sold as ''100 percent organic,'' ''organic,'' or ''made with * * *'' when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance. Commenters believe that organic certifying agents may be required to test many nonorganic agricultural inputs (such as seeds, compost, straw, sawdust, and plastic) and nonorganic agricultural products and ingredients used in products labeled as ''made with * * *''. They also argued that such testing would be unnecessary, burdensome, and expensive because such materials are more likely to have come into contact with a prohibited substance. Therefore, commenters suggested that we amend section 205.670(b) by deleting ''agricultural inputs'' and replacing ''agricultural product'' with ''organically produced agricultural product.'' They also recommended that we replace the second occurrence of ''product'' with ''organic product.'' Thus section 205.670(b) would suggest that only *organic* agricultural products could be required to be tested by the certifying agent.

We understand the concerns of the commenters but believe that the commenters have misinterpreted the intent of section 205.670(b). It is not our intent to mandate residue testing of all inputs and ingredients used in the production of organic agricultural products. Neither is it our intent for certifying agents to abuse residue testing responsibility by conducting residue tests of certified organic operations without reason to believe that the agricultural input or product intended to be sold as organic has come into contact with prohibited substances. Our intent is to make it clear that certifying agents have the authority to test any agricultural input used or agricultural product intended to be sold as organically produced when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance. Section 205.670(b) allows for testing of inputs and agricultural products, but it does not require that all inputs of a product intended to be sold as organically produced must be tested. However, certifying agents must be able to ensure that certified organic operations are operating in accordance with the Act and the regulations set forth in this part. To assure that certifying agents have established fair and effective procedures for enforcing residue testing requirements, section 205.504(b)(6) provides that they must submit to USDA a copy of the procedures to be used for

sampling and residue testing pursuant to section 205.670.

(2) *Chain Of Custody Training.* A commenter suggested that section 205.670(c) address chain of custody training for inspectors that will be performing preharvest or postharvest tissue test sample collection on behalf of the Administrator, SOP's governing State official, or certifying agent. The commenter proposed that all inspectors should be trained to handle chain of custody samples in order to maintain the integrity of the samples.

We agree that inspectors should be appropriately trained to handle chain-of-custody samples in order to maintain the integrity of the samples taken from a certified organic operation. However, we do not believe that the language in section 205.670(c) must be modified to address such an issue. As a USDA-accredited body, a private or State entity operating as a certifying agent must ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned. The certifying agent must also submit a description of the training that has been provided or intends to be provided to personnel to ensure that they comply with and implement the requirements of the Act and the regulations in this part. In addition, certifying agents must submit a copy of the procedure to be used for sampling and residue testing for approval by the Administrator. Through the accreditation process, therefore, we will be able to assess the expertise of the individuals employed by the certifying agent and provide guidance in areas where additional training is needed to comply with the requirements of the Act and the regulations in this part.

(3) *Exclusion from Organic Sale.* Commenters expressed that section 205.671(a) could be easily misinterpreted. They said that section 205.671(a) did not make clear that residue testing may not be used to qualify crops to be sold as organic if a direct application of prohibited materials occurred. Commenters suggested that section 205.671(a) include: ''Any crop or product to which prohibited materials have been directly applied shall not be sold, labeled, or represented as organically produced.''

We do not believe this additional language is necessary. Residue testing cannot be used to qualify any agricultural crop or product to which a prohibited material has been purposefully/directly applied. The presence of any prohibited substance on an agricultural product to be sold as organic warrants an investigation as to why the detected prohibited substance is present on the agricultural product. It does not matter if the product has come into contact with a prohibited substance through means of drift or intentional application. If the outcome of the investigation reveals that the presence of the detected prohibited substance is the result of an intentional application, the certified operation will be subject to suspension or revocation of its organic certification and/or a civil penalty of not more than $10,000 if he/she knowingly sells the product as organic. The use of prohibited substances is not allowed in the Act or this final rule. Residue testing is not a means of qualifying a crop or product as organic if a prohibited substance has been intentionally/directly applied. It is a tool for monitoring compliance with the regulations set forth in the Act and in this part.

(4) *Emergency Pest or Disease Treatment Programs.* Commenters requested that we make a clear distinction between crops or agricultural products that have had prohibited substances directly applied to them and those that have come into contact with prohibited substances through chemical drift. They have proposed that we amend section 205.672(a) to address this issue. Section 205.672(a) of the proposal states that any harvested crop or plant part to be harvested that has had contact with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program cannot be sold as organically produced. Commenters did not find this language acceptable because it did not distinguish between the two types of ways that products can come into contact with prohibited substances (drift and direct/intentional application) and how each situation would be addressed with respect to the national organic standards. Commenters believed that section 205.672(a) was fairly ambiguous and open for misinterpretation. Commenters requested that we amend language in section 205.672(a) to include that ''Any harvested crop or plant part to be harvested that has contact with a prohibited substance *directly applied* to the crop as the result of a Federal or State emergency pest or disease treatment program cannot be sold, labeled, or represented as organically produced.''

We do not accept the commenters' request and believe that the commenters have misinterpreted section 205.672 of the proposed rule. Section 205.672 specifically addresses certified organic operations that have had prohibited substances applied to them due to a Federal or State pest or disease treatment program. Section 205.672 does not include those organic operations that may have been drifted upon by prohibited substances that have been applied to a neighboring farm as a result of a Federal or State emergency pest or disease treatment program. Any potential drift from a mandatory pest and disease treatment program will be treated in the same manner as drift from any other source.

Adverse Action Appeal Process

This portion of subpart G sets forth the procedures for appealing adverse actions under the National Organic Program (NOP). These procedures will be used by: (1) Producers and handlers appealing denial of certification and proposed suspension or revocation of certification decisions; and (2) certifying agents appealing denial of accreditation and proposed suspension or revocation of accreditation decisions. The Act and the Administrative Procedure Act (APA) (5 U.S.C. 553–559) provides affected persons with the right to appeal any adverse actions taken against their application for certification or accreditation or their certification or accreditation.

The Administrator will handle certification appeals from operations in States that do not have an approved State organic program (SOP). The Administrator will also handle appeals of accreditation decisions of the NOP Program Manager. The Administrator will issue decisions to sustain or deny appeals. If an appeal is denied, the Administrator will initiate a formal adjudicatory proceeding to deny, suspend, or revoke certification or accreditation. Such proceedings will be conducted pursuant to USDA's Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes, 7 CFR 1.130 through 1.151. Under these rules of practice, if the Administrative Law Judge denies the appeal, the appellant may appeal the Administrative Law Judge's decision to the Judicial Officer. If the Judicial Officer denies the appeal, the appellant may appeal the Judicial Officer's decision to the United States District Court for the district in which the appellant is located.

In States with approved SOP's, the SOP will oversee certification compliance proceedings and handle appeals from certified operations in the State. An SOP's appeal procedures and rules of procedure must be approved by the Secretary and must be equivalent to

those of the NOP and USDA. The final decision on an appeal under the SOP may be appealed by the appellant to United States District Court for the district in which the appellant is located.

Description of Regulations

These appeal procedures provide that: (1) Persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of the NOP's Program Manager may appeal such decision to the Administrator; (2) persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of an SOP may appeal such decision to the SOP's governing State official who will initiate handling of the appeal in accordance with the appeal procedures approved by the Secretary; and (3) persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of a certifying agent may appeal such decision to the Administrator unless the person is subject to an approved SOP, in which case the appeal must be made to the SOP.

All written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts. All appeals filed under these procedures will be reviewed, heard, and decided by persons not involved with the decision being appealed.

Certification Appeals

Applicants for certification may appeal a certifying agent's notice of denial of certification. Certified operations may appeal a notification of proposed suspension or revocation of their certification issued by their certifying agent. Such appeals will be made to the Administrator unless the person is subject to an approved SOP, in which case the appeal must be made to the SOP.

If the Administrator or SOP sustains an appeal, the applicant or certified operation will be granted certification or continued certification, as applicable to the operation's status. The act of sustaining the appeal will not be considered an adverse action and may not be appealed by the certifying agent which issued the notice of denial of certification or notification of proposed suspension or revocation of certification.

If the Administrator or SOP denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the certification. Such proceeding will be conducted in accordance with USDA's Uniform Rules of Practice or the SOP's rules of procedure.

Accreditation Appeals

Applicants for accreditation may appeal the Program Manager's notification of accreditation denial. Accredited certifying agents may appeal a notification of proposed suspension or revocation of their accreditation issued by the Program Manager. Such appeals will be made to the Administrator. If the Administrator sustains an appeal, the applicant or certifying agent will be granted accreditation or continued accreditation, as applicable to the operation's status. If the Administrator denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the accreditation. Such proceeding will be conducted in accordance with USDA's Uniform Rules of Practice.

Filing Period

An appeal of a noncompliance decision must be filed within the time period provided in the letter of notification or within 30 days from the date of receipt of the notification, whichever occurs later. The appeal will be considered ''filed'' on the date received by the Administrator or, when applicable, the SOP. Unless appealed in a timely manner, a notification to deny, suspend, or revoke a certification or accreditation will become final. The applicant, certified operation, or certifying agent that does not file an appeal in the time period provided waives the right to further appeal of the compliance proceeding.

Where and What to File

Appeals to the Administrator must be filed in writing and sent to: Administrator, USDA–AMS, Room 3071–S, P.O. Box 96456, Washington, DC 20090–6456. Appeals to the SOP must be filed in writing to the address and person identified in the letter of notification. All appeals must include a copy of the adverse decision to be reviewed and a statement of the appellant's reasons for believing that the decision was not proper or made in accordance with applicable program regulations, policies, or procedures.

Appeals—Changes Based On Comments

This portion of subpart G differs from the proposal in several respects as follows:

(1) *To Whom an Appeal Is Made.* We have amended section 205.680 to clarify to whom an appeal is made when the noncompliance decision is made by the NOP's Program Manager, an SOP, or a certifying agent. Several commenters requested that we amend section 205.680 to make it consistent with the provision providing that appeals to the Administrator are not allowed in the case of an SOP decision, because such appeals have to be made to the SOP's governing State official.

We agree that section 205.680 did not convey sufficient explanation of to whom an appeal is made. Accordingly, we have amended the language in section 205.680 to clarify through paragraphs (a), (b), and (c) that: (1) Persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of the NOP's Program Manager may appeal such decision to the Administrator; (2) persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of an SOP may appeal such decision to the SOP's governing State official who will initiate handling of the appeal pursuant to appeal procedures approved by the Secretary; and (3) persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of a certifying agent may appeal such decision to the Administrator unless the person is subject to an approved SOP, in which case the appeal must be made to the SOP.

(2) *Written Communications.* We have added a new paragraph (d) to section 205.680, which provides that all written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts. We have taken this action to further clarify the appeals process. This addition to section 205.680 implements the same requirements for appeal documents as our addition of new paragraph (d) to section 205.660 stipulates for compliance documents.

(3) *Who Shall Handle Appeals.* We have added a new paragraph (e) to section 205.680, which provides that all appeals must be reviewed, heard, and decided by persons not involved with the decision being appealed. This provision was added to section 205.680 to allay the fears of commenters that the person making the decision would be the person deciding the appeal. A couple of commenters recommended that an appeal be heard by persons other than those who made the decision being appealed. Specifically, they want the appeal conducted by independent hearing officers who are not responsible for implementation or administration of the NOP. They also want the final decision-making authority in the administrative review process placed in the hands of the Secretary.

Under the NOP, once the compliance procedures are completed at the certifying agent level, the certified operation may appeal the decision of the certifying agent to the Administrator or to the SOP when the certified operation is located within a State with an approved SOP. The Administrator or the SOP will review the case and render an opinion on the appeal. When the appeal is sustained, the certified operation and certifying agent are notified and the case ends. However, if the appeal is denied the certified operation and certifying agent are notified and the certified operation is given an opportunity to appeal the decision of the Administrator or SOP.

Appeals of decisions made by the Administrator will be heard by an Administrative Law Judge. If the Administrative Law Judge rules against the certified operation, the Administrative Law Judge's decision may be appealed by the certified operation to the Judicial Officer. The Judicial Officer is the USDA official delegated authority by the Secretary as the final deciding officer in adjudication proceedings. If the Judicial Officer rules against the certified operation, the Judicial Officer's decision may be appealed by the certified operation to the United States District Court for the district in which the certified operation is located. For additional information see USDA's Uniform Rules of Practice found at 7 CFR part 1, subpart H.

Appeals of decisions made by an SOP will follow procedures comparable to those just described for an appeal of a decision made by the Administrator. As with a final decision of USDA, a final decision of the State that goes against the certified operation may be appealed to the United States District Court for the district in which the certified operation is located.

(4) *Filing Period.* We have amended the first sentence of section 205.681(c) by replacing ''at least'' with ''within'' and by adding the words, ''whichever occurs later,'' to the end thereof. This amendment has been made to clarify our intent that persons affected by a noncompliance proceeding decision receive not less than 30 days in which to file their appeal of the decision.

(5) *Where To File an Appeal.* We have amended section 205.681(d) to clarify where appeals are to be filed. First, we have amended what is now paragraph (1) by removing the requirement that the appellant send a copy of the appeal to the certifying agent. This action shifts the responsibility of notifying the certifying agent of the appeal from the appellant to USDA or, when applicable, the SOP. Second, we have added language at paragraph (2) which clarifies that appeals to the SOP must be filed in writing to the address and person identified in the letter of notification. Finally, we have amended what is now paragraph (3) of section 205.681 by replacing ''position'' with ''reasons for believing'' to clarify the intended scope and purpose of the appellant's appeal statement. Clarification of section 205.681(d) was prompted by a commenter who stated that it is discriminatory to require clients of private certifying agents to appeal to USDA in Washington, when State program clients can appeal locally.

There are various levels of appeal within the NOP. Clients of certifying agents (State and private) are provided with an opportunity to rebut the noncompliance findings of the certifying agent. Once the certified operation has exhausted its options at the certifying agent level, the certified operation may appeal the decision of the certifying agent to the Administrator or to the SOP when the certified operation is located within a State with an approved SOP.

The Administrator will review the case and render an opinion on the appeal. This level of appeal will not require the certified operation's representative to travel to the Administrator. An appeal of a decision made by the Administrator will be heard by an Administrative Law Judge as near as possible to the certified operation's representative's place of business or residence. An appeal of a decision made by the Administrative Law Judge will be heard by the Judicial Officer. Again the certified operation's representative will not be required to travel outside of the representative's place of business or residence. If the certified operation appeals the decision of the Judicial Officer, the appeal would be heard by the United States District Court for the district in which the certified operation is located.

Appeals of decisions made by an SOP will follow procedures comparable to those just described for an appeal of a decision made by the Administrator. As with a final decision of USDA, a final decision of the State that goes against the certified operation may be appealed to the United States District Court for the district in which the certified operation is located.

(6) *Appeal Reports.* We will submit an annual report on appeals to the National Organic Standards Board (NOSB), which will include nonconfidential compliance information. A commenter requested that we report quarterly to the NOSB on appeals (number, outcome, kinds, and problems). We agree that it would be appropriate for the NOP to submit an appeals report to the NOSB. We will compile appeal data such as the number, outcome, kinds, and problems encountered. We will maintain this information under the compliance program to be developed within the NOP. We do not believe that it is necessary to put this type of detail or activity into the regulations. Further, we do not believe, at this time, that reporting more frequently than annually will be needed. The NOP, however, will work closely with the NOSB to provide it with the information it may need to recommend program amendments designed to address compliance and appeal issues.

(7) *Availability of Appeal Information.* We will develop and distribute appeal information. A commenter requested that section 205.680 be amended to require the distribution of an appeal information brochure to any applicant for accreditation or certification. We agree that the development and distribution of such information is a good idea. We do not believe, however, that it is necessary or appropriate to put this type of detail or activity into the regulations. We plan to provide program information, including appeals and related issues, on the NOP website.

Appeals—Changes Requested But Not Made

This portion of subpart G retains from the proposed rule, regulations on which we received comments as follows:

(1) *National Appeals Division.* Several commenters recommend amending sections 205.680 and 205.681 to provide for appeals to the National Appeals Division under the provisions at 7 CFR part 11. We disagree with the request that the NOP use the National Appeals Division Rules of Procedure. The Act and its implementing regulations are subject to the APA for rulemaking and adjudication. The provisions of the APA generally applicable to agency adjudication are not applicable to proceedings under 7 CFR part 11, National Appeals Division Rules of Procedure. USDA uses 7 CFR part 1, Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes, for adjudicatory proceedings involving the denial, suspension, and revocation of certification and accreditation.

Appeals—Clarifications

Clarification is given on the following issues raised by commenters:

(1) *Appeals.* A commenter stated that appeals of certification decisions should always be taken first to the certifying

agent to provide an opportunity to rectify any possible error. Another commenter requested an appeals process that includes private certifying agents.

Section 205.662(a) requires a written notification of noncompliance with opportunity to rebut or correct. When the noncompliance has been resolved due to rebuttal or correction, a written notification of noncompliance resolution is issued in accordance with section 205.662(b). When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, a written notification of proposed suspension or revocation will be issued in accordance with section 205.662(c). This notification will advise the certified operation of its right to request mediation or file an appeal with the Administrator or, when applicable, an SOP. We believe this process of providing a notification of noncompliance with opportunity to rebut or correct, followed by a notification of proposed suspension or revocation, provides ample opportunity for the certified operation to work with its certifying agent to resolve issues of noncompliance.

(2) *Timely Notification.* A few commenters requested that we amend section 205.680 to include mandatory procedures for timely written notice of an adverse decision, the reasons for the decision, the person's appeal rights, and the procedures for filing an appeal. We recognize that all compliance activities need to be carried out as quickly and expeditiously as possible within the confines of due process. We believe that the commenters' concerns are addressed through various sections of these regulations. Section 205.402(a) requires review of an application upon acceptance of the application. Section 205.405, on denial of certification, requires a notification of noncompliance, followed, as applicable, by a notice of denial of certification. In accordance with section 205.405(d), the notice of denial of certification will state the reasons for denial and the applicant's right to request mediation or appeal the decision. Section 205.507 on denial of accreditation requires a notification of noncompliance, followed, as applicable, by a denial of accreditation. The notification of accreditation denial will state the reasons for denial and the applicant's right to appeal the decision. Compliance sections 205.662 for certified operations and 205.665 for certifying agents require a notification of noncompliance with an opportunity to correct or rebut the noncompliance(s). Sections 205.662 and 205.665, when applicable, require the issuance of a notification of proposed suspension or revocation. Such notice must describe the noncompliance and the entity's right to an appeal. Section 205.681 provides the procedures for filling an appeal.

Miscellaneous

Section 205.690 provisions the Office of Management and Budget control number assigned to the information collection requirements of these regulations. Sections 205.691 through 205.699 are reserved.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, Title 7, Chapter I of the Code of Federal Regulations is amended as follows:

PARTS 205–209 [REMOVED]

1. Parts 205 through 209, which are currently reserved in subchapter K (Federal Seed Act), are removed.

2. A new subchapter M consisting of parts 205 through 209 is added to read as follows:

SUBCHAPTER M—ORGANIC FOODS PRODUCTION ACT PROVISIONS

PART 205—NATIONAL ORGANIC PROGRAM

Subpart A—Definitions

Sec.

Subpart B—Applicability

Subpart C—Organic Production and Handling Requirements

Subpart D—Labels, Labeling, and Market Information

Subpart E—Certification

Subpart F—Accreditation of Certifying Agents

Authority: 7 U.S.C. 6501–6522.

Subpart A—Definitions

§ 205.1 Meaning of words.

For the purpose of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand.

§ 205.2 Terms defined.

Accreditation. A determination made by the Secretary that authorizes a private, foreign, or State entity to conduct certification activities as a certifying agent under this part.

Act. The Organic Foods Production Act of 1990, as amended (7 U.S.C. 6501 et seq.).

Action level. The limit at or above which the Food and Drug Administration will take legal action against a product to remove it from the market. Action levels are based on unavoidability of the poisonous or deleterious substances and do not represent permissible levels of contamination where it is avoidable.

Administrator. The Administrator for the Agricultural Marketing Service, United States Departure of Agriculture, or the representative to whom authority has been delegated to act in the stead of the Administrator.

Agricultural inputs. All substances or materials used in the production or handling of organic agricultural products.

Agricultural product. Any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketed in the United States for human or livestock consumption.

Agricultural Marketing Service (AMS). The Agricultural Marketing Service of the United States Department of Agriculture.

Allowed synthetic. A substance that is included on the National List of synthetic substances allowed for use in organic production or handling.

Animal drug. Any drug as defined in section 201 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 321), that is intended for use in livestock, including any drug intended for use in livestock feed but not including such livestock feed.

Annual seedling. A plant grown from seed that will complete its life cycle or produce a harvestable yield within the same crop year or season in which it was planted.

Area of operation. The types of operations: crops, livestock, wild-crop harvesting or handling, or any combination thereof that a certifying agent may be accredited to certify under this part.

Audit trail. Documentation that is sufficient to determine the source, transfer of ownership, and transportation of any agricultural product labeled as ''100 percent organic,'' the organic ingredients of any agricultural product labeled as ''organic'' or ''made with organic (specified ingredients)'' or the organic ingredients of any agricultural product containing less than 70 percent organic ingredients identified as organic in an ingredients statement.

Biodegradable. Subject to biological decomposition into simpler biochemical or chemical components.

Biologics. All viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms, and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals.

Breeder stock. Female livestock whose offspring may be incorporated into an organic operation at the time of their birth.

Buffer zone. An area located between a certified production operation or portion of a production operation and an adjacent land area that is not maintained under organic management. A buffer zone must be sufficient in size or other features (e.g., windbreaks or a diversion ditch) to prevent the possibility of unintended contact by prohibited substances applied to adjacent land areas with an area that is part of a certified operation.

Bulk. The presentation to consumers at retail sale of an agricultural product in unpackaged, loose form, enabling the consumer to determine the individual pieces, amount, or volume of the product purchased.

Certification or certified. A determination made by a certifying agent that a production or handling operation is in compliance with the Act and the regulations in this part, which is documented by a certificate of organic operation.

Certified operation. A crop or livestock production, wild-crop harvesting or handling operation, or portion of such operation that is certified by an accredited certifying agent as utilizing a system of organic production or handling as described by the Act and the regulations in this part.

Certifying agent. Any entity accredited by the Secretary as a certifying agent for the purpose of certifying a production or handling operation as a certified production or handling operation.

Certifying agent's operation. All sites, facilities, personnel, and records used by a certifying agent to conduct certification activities under the Act and the regulations in this part.

Claims. Oral, written, implied, or symbolic representations, statements, or advertising or other forms of communication presented to the public or buyers of agricultural products that relate to the organic certification process or the term, ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients or food group(s)),'' or, in the case of agricultural products containing less than 70 percent organic ingredients, the term, ''organic,'' on the ingredients panel.

Commercially available. The ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.

Commingling. Physical contact between unpackaged organically produced and nonorganically produced agricultural products during production, processing, transportation, storage or handling, other than during the manufacture of a multiingredient product containing both types of ingredients.

Compost. The product of a managed process through which microorganisms break down plant and animal materials into more available forms suitable for application to the soil. Compost must be produced through a process that combines plant and animal materials with an initial C:N ratio of between 25:1 and 40:1. Producers using an in-vessel or static aerated pile system must maintain the composting materials at a temperature between 131° F and 170° F for 3 days. Producers using a windrow system must maintain the composting materials at a temperature between 131° F and 170° F for 15 days, during which time, the materials must be turned a minimum of five times.

Control. Any method that reduces or limits damage by populations of pests, weeds, or diseases to levels that do not significantly reduce productivity.

Crop. A plant or part of a plant intended to be marketed as an agricultural product or fed to livestock.

Crop residues. The plant parts remaining in a field after the harvest of a crop, which include stalks, stems, leaves, roots, and weeds.

Crop rotation. The practice of alternating the annual crops grown on a specific field in a planned pattern or sequence in successive crop years so that crops of the same species or family are not grown repeatedly without interruption on the same field. Perennial cropping systems employ means such as alley cropping, intercropping, and hedgerows to introduce biological diversity in lieu of crop rotation.

Crop year. That normal growing season for a crop as determined by the Secretary.

Cultivation. Digging up or cutting the soil to prepare a seed bed; control weeds; aerate the soil; or work organic matter, crop residues, or fertilizers into the soil.

Cultural methods. Methods used to enhance crop health and prevent weed, pest, or disease problems without the use of substances; examples include the selection of appropriate varieties and planting sites; proper timing and density of plantings; irrigation; and extending a growing season by manipulating the microclimate with green houses, cold frames, or wind breaks.

Detectable residue. The amount or presence of chemical residue or sample component that can be reliably observed or found in the sample matrix by current approved analytical methodology.

Disease vectors. Plants or animals that harbor or transmit disease organisms or pathogens which may attack crops or livestock.

Drift. The physical movement of prohibited substances from the intended target site onto an organic operation or portion thereof.

Emergency pest or disease treatment program. A mandatory program authorized by a Federal, State, or local agency for the purpose of controlling or eradicating a pest or disease.

Employee. Any person providing paid or volunteer services for a certifying agent.

Excluded methods. A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

Feed. Edible materials which are consumed by livestock for their nutritional value. Feed may be concentrates (grains) or roughages (hay, silage, fodder). The term, ''feed,'' encompasses all agricultural commodities, including pasture ingested by livestock for nutritional purposes.

Feed additive. A substance added to feed in micro quantities to fulfill a specific nutritional need; i.e., essential nutrients in the form of amino acids, vitamins, and minerals.

Feed supplement. A combination of feed nutrients added to livestock feed to improve the nutrient balance or performance of the total ration and intended to be:

(1) Diluted with other feeds when fed to livestock;

(2) Offered free choice with other parts of the ration if separately available; or

(3) Further diluted and mixed to produce a complete feed.

Fertilizer. A single or blended substance containing one or more recognized plant nutrient(s) which is used primarily for its plant nutrient content and which is designed for use or claimed to have value in promoting plant growth.

Field. An area of land identified as a discrete unit within a production operation.

Forage. Vegetative material in a fresh, dried, or ensiled state (pasture, hay, or silage), which is fed to livestock.

Governmental entity. Any domestic government, tribal government, or foreign governmental subdivision providing certification services.

Handle. To sell, process, or package agricultural products, except such term shall not include the sale, transportation, or delivery of crops or livestock by the producer thereof to a handler.

Handler. Any person engaged in the business of handling agricultural products, including producers who handle crops or livestock of their own production, except such term shall not include final retailers of agricultural products that do not process agricultural products.

Handling operation. Any operation or portion of an operation (except final retailers of agricultural products that do not process agricultural products) that receives or otherwise acquires agricultural products and processes, packages, or stores such products.

Immediate family. The spouse, minor children, or blood relatives who reside in the immediate household of a certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent. For the purpose of this part, the interest of a spouse, minor child, or blood relative who is a resident of the immediate household of a certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent shall be considered to be an interest of the certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent.

Inert ingredient. Any substance (or group of substances with similar chemical structures if designated by the Environmental Protection Agency) other than an active ingredient which is intentionally included in any pesticide product (40 CFR 152.3(m)).

Information panel. That part of the label of a packaged product that is immediately contiguous to and to the right of the principal display panel as observed by an individual facing the principal display panel, unless another section of the label is designated as the information panel because of package size or other package attributes (e.g., irregular shape with one usable surface).

Ingredient. Any substance used in the preparation of an agricultural product that is still present in the final commercial product as consumed.

Ingredients statement. The list of ingredients contained in a product shown in their common and usual names in the descending order of predominance.

Inspection. The act of examining and evaluating the production or handling operation of an applicant for certification or certified operation to determine compliance with the Act and the regulations in this part.

Inspector. Any person retained or used by a certifying agent to conduct inspections of certification applicants or certified production or handling operations.

Label. A display of written, printed, or graphic material on the immediate container of an agricultural product or any such material affixed to any agricultural product or affixed to a bulk container containing an agricultural product, except for package liners or a display of written, printed, or graphic material which contains only information about the weight of the product.

Labeling. All written, printed, or graphic material accompanying an agricultural product at any time or written, printed, or graphic material about the agricultural product displayed at retail stores about the product.

Livestock. Any cattle, sheep, goat, swine, poultry, or equine animals used for food or in the production of food, fiber, feed, or other agricultural-based consumer products; wild or domesticated game; or other nonplant life, except such term shall not include aquatic animals or bees for the production of food, fiber, feed, or other agricultural-based consumer products.

Lot. Any number of containers which contain an agricultural product of the same kind located in the same conveyance, warehouse, or packing house and which are available for inspection at the same time.

Manure. Feces, urine, other excrement, and bedding produced by livestock that has not been composted.

Market information. Any written, printed, audiovisual, or graphic information, including advertising, pamphlets, flyers, catalogues, posters, and signs, distributed, broadcast, or made available outside of retail outlets that are used to assist in the sale or promotion of a product.

Mulch. Any nonsynthetic material, such as wood chips, leaves, or straw, or any synthetic material included on the National List for such use, such as newspaper or plastic that serves to suppress weed growth, moderate soil temperature, or conserve soil moisture.

Narrow range oils. Petroleum derivatives, predominately of paraffinic and napthenic fractions with 50 percent boiling point (10 mm Hg) between 415° F and 440° F.

National List. A list of allowed and prohibited substances as provided for in the Act.

National Organic Program (NOP). The program authorized by the Act for the purpose of implementing its provisions.

National Organic Standards Board (NOSB). A board established by the Secretary under 7 U.S.C. 6518 to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of the National Organic Program.

Natural resources of the operation. The physical, hydrological, and biological features of a production operation, including soil, water, wetlands, woodlands, and wildlife.

Nonagricultural substance. A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.

Nonsynthetic (natural). A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, nonsynthetic is used as a synonym for natural as the term is used in the Act.

Nonretail container. Any container used for shipping or storage of an agricultural product that is not used in the retail display or sale of the product.

Nontoxic. Not known to cause any adverse physiological effects in animals, plants, humans, or the environment.

Organic. A labeling term that refers to an agricultural product produced in accordance with the Act and the regulations in this part.

Organic matter. The remains, residues, or waste products of any organism.

Organic production. A production system that is managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.

Organic system plan. A plan of management of an organic production or handling operation that has been agreed to by the producer or handler and the certifying agent and that includes written plans concerning all aspects of agricultural production or handling described in the Act and the regulations in subpart C of this part.

Pasture. Land used for livestock grazing that is managed to provide feed value and maintain or improve soil, water, and vegetative resources.

Peer review panel. A panel of individuals who have expertise in organic production and handling methods and certification procedures and who are appointed by the Administrator to assist in evaluating applicants for accreditation as certifying agents.

Person. An individual, partnership, corporation, association, cooperative, or other entity.

Pesticide. Any substance which alone, in chemical combination, or in any formulation with one or more substances is defined as a pesticide in

section 2(u) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136(u) *et seq*).

Petition. A request to amend the National List that is submitted by any person in accordance with this part.

Planting stock. Any plant or plant tissue other than annual seedlings but including rhizomes, shoots, leaf or stem cuttings, roots, or tubers, used in plant production or propagation.

Practice standard. The guidelines and requirements through which a production or handling operation implements a required component of its production or handling organic system plan. A practice standard includes a series of allowed and prohibited actions, materials, and conditions to establish a minimum level performance for planning, conducting, and maintaining a function, such as livestock health care or facility pest management, essential to an organic operation.

Principal display panel. That part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for sale.

Private entity. Any domestic or foreign nongovernmental for-profit or not-for-profit organization providing certification services.

Processing. Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container.

Processing aid. (1) Substance that is added to a food during the processing of such food but is removed in some manner from the food before it is packaged in its finished form;

(2) a substance that is added to a food during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; and

(3) a substance that is added to a food for its technical or functional effect in the processing but is present in the finished food at insignificant levels and does not have any technical or functional effect in that food.

Producer. A person who engages in the business of growing or producing food, fiber, feed, and other agricultural-based consumer products.

Production lot number/identifier. Identification of a product based on the production sequence of the product showing the date, time, and place of production used for quality control purposes.

Prohibited substance. A substance the use of which in any aspect of organic production or handling is prohibited or not provided for in the Act or the regulations of this part.

Records. Any information in written, visual, or electronic form that documents the activities undertaken by a producer, handler, or certifying agent to comply with the Act and regulations in this part.

Residue testing. An official or validated analytical procedure that detects, identifies, and measures the presence of chemical substances, their metabolites, or degradations products in or on raw or processed agricultural products.

Responsibly connected. Any person who is a partner, officer, director, holder, manager, or owner of 10 percent or more of the voting stock of an applicant or a recipient of certification or accreditation.

Retail food establishment. A restaurant; delicatessen; bakery; grocery store; or any retail outlet with an in-store restaurant, delicatessen, bakery, salad bar, or other eat-in or carry-out service of processed or prepared raw and ready-to-eat-food.

Routine use of parasiticide. The regular, planned, or periodic use of parasiticides.

Secretary. The Secretary of Agriculture or a representative to whom authority has been delegated to act in the Secretary's stead.

Sewage sludge. A solid, semisolid, or liquid residue generated during the treatment of domestic sewage in a treatment works. Sewage sludge includes but is not limited to: domestic septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from sewage sludge. Sewage sludge does not include ash generated during the firing of sewage sludge in a sewage sludge incinerator or grit and screenings generated during preliminary treatment of domestic sewage in a treatment works.

Slaughter stock. Any animal that is intended to be slaughtered for consumption by humans or other animals.

Soil and water quality. Observable indicators of the physical, chemical, or biological condition of soil and water, including the presence of environmental contaminants.

Split operation. An operation that produces or handles both organic and nonorganic agricultural products.

State. Any of the several States of the United States of America, its territories, the District of Columbia, and the Commonwealth of Puerto Rico.

State certifying agent. A certifying agent accredited by the Secretary under the National Organic Program and operated by the State for the purposes of certifying organic production and handling operations in the State.

State organic program (SOP). A State program that meets the requirements of section 6506 of the Act, is approved by the Secretary, and is designed to ensure that a product that is sold or labeled as organically produced under the Act is produced and handled using organic methods.

State organic program's governing State official. The chief executive official of a State or, in the case of a State that provides for the statewide election of an official to be responsible solely for the administration of the agricultural operations of the State, such official who administers a State organic certification program.

Synthetic. A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

Tolerance. The maximum legal level of a pesticide chemical residue in or on a raw or processed agricultural commodity or processed food.

Transplant. A seedling which has been removed from its original place of production, transported, and replanted.

Unavoidable residual environmental contamination (UREC). Background levels of naturally occurring or synthetic chemicals that are present in the soil or present in organically produced agricultural products that are below established tolerances.

Wild crop. Any plant or portion of a plant that is collected or harvested from a site that is not maintained under cultivation or other agricultural management.

Subpart B—Applicability

§ 205.100 What has to be certified.

(a) Except for operations exempt or excluded in § 205.101, each production or handling operation or specified portion of a production or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients or food group(s))'' must be certified according to the provisions of subpart E of this part and

must meet all other applicable requirements of this part.

(b) Any production or handling operation or specified portion of a production or handling operation that has been already certified by a certifying agent on the date that the certifying agent receives its accreditation under this part shall be deemed to be certified under the Act until the operation's next anniversary date of certification. Such recognition shall only be available to those operations certified by a certifying agent that receives its accreditation within 18 months from February 20, 2001.

(c) Any operation that:

(1) Knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than $10,000 per violation.

(2) Makes a false statement under the Act to the Secretary, a governing State official, or an accredited certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.

§ 205.101 Exemptions and exclusions from certification.

(a) *Exemptions.* (1) A production or handling operation that sells agricultural products as ''organic'' but whose gross agricultural income from organic sales totals $5,000 or less annually is exempt from certification under subpart E of this part and from submitting an organic system plan for acceptance or approval under § 205.201 but must comply with the applicable organic production and handling requirements of subpart C of this part and the labeling requirements of § 205.310. The products from such operations shall not be used as ingredients identified as organic in processed products produced by another handling operation.

(2) A handling operation that is a retail food establishment or portion of a retail food establishment that handles organically produced agricultural products but does not process them is exempt from the requirements in this part.

(3) A handling operation or portion of a handling operation that only handles agricultural products that contain less than 70 percent organic ingredients by total weight of the finished product (excluding water and salt) is exempt from the requirements in this part, except:

(i) The provisions for prevention of contact of organic products with prohibited substances set forth in § 205.272 with respect to any organically produced ingredients used in an agricultural product;

(ii) The labeling provisions of §§ 205.305 and 205.310; and

(iii) The recordkeeping provisions in paragraph (c) of this section.

(4) A handling operation or portion of a handling operation that only identifies organic ingredients on the information panel is exempt from the requirements in this part, except:

(i) The provisions for prevention of contact of organic products with prohibited substances set forth in § 205.272 with respect to any organically produced ingredients used in an agricultural product;

(ii) The labeling provisions of §§ 205.305 and 205.310; and

(iii) The recordkeeping provisions in paragraph (c) of this section.

(b) *Exclusions.* (1) A handling operation or portion of a handling operation is excluded from the requirements of this part, except for the requirements for the prevention of commingling and contact with prohibited substances as set forth in § 205.272 with respect to any organically produced products, if such operation or portion of the operation only sells organic agricultural products labeled as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients or food group(s))'' that:

(i) Are packaged or otherwise enclosed in a container prior to being received or acquired by the operation; and

(ii) Remain in the same package or container and are not otherwise processed while in the control of the handling operation.

(2) A handling operation that is a retail food establishment or portion of a retail food establishment that processes, on the premises of the retail food establishment, raw and ready-to-eat food from agricultural products that were previously labeled as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients or food group(s))'' is excluded from the requirements in this part, except:

(i) The requirements for the prevention of contact with prohibited substances as set forth in § 205.272; and

(ii) The labeling provisions of § 205.310.

(c) *Records to be maintained by exempt operations.* (1) Any handling operation exempt from certification pursuant to paragraph (a)(3) or (a)(4) of this section must maintain records sufficient to:

(i) Prove that ingredients identified as organic were organically produced and handled; and

(ii) Verify quantities produced from such ingredients.

(2) Records must be maintained for no less than 3 years beyond their creation and the operations must allow representatives of the Secretary and the applicable State organic programs' governing State official access to these records for inspection and copying during normal business hours to determine compliance with the applicable regulations set forth in this part.

§ 205.102 Use of the term, ''organic.''

Any agricultural product that is sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients or food group(s))'' must be:

(a) Produced in accordance with the requirements specified in § 205.101 or §§ 205.202 through 205.207 or §§ 205.236 through 205.239 and all other applicable requirements of part 205; and

(b) Handled in accordance with the requirements specified in § 205.101 or §§ 205.270 through 205.272 and all other applicable requirements of this part 205.

§ 205.103 Recordkeeping by certified operations.

(a) A certified operation must maintain records concerning the production, harvesting, and handling of agricultural products that are or that are intended to be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients or food group(s)).''

(b) Such records must:

(1) Be adapted to the particular business that the certified operation is conducting;

(2) Fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited;

(3) Be maintained for not less than 5 years beyond their creation; and

(4) Be sufficient to demonstrate compliance with the Act and the regulations in this part.

(c) The certified operation must make such records available for inspection and copying during normal business hours by authorized representatives of the Secretary, the applicable State program's governing State official, and the certifying agent.

§ 205.104 [Reserved]

§ 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

To be sold or labeled as ''100 percent organic,'' ''organic,'' or ''made with

organic (specified ingredients or food group(s)),'' the product must be produced and handled without the use of:

(a) Synthetic substances and ingredients, except as provided in § 205.601 or § 205.603;

(b) Nonsynthetic substances prohibited in § 205.602 or § 205.604;

(c) Nonagricultural substances used in or on processed products, except as otherwise provided in § 205.605;

(d) Nonorganic agricultural substances used in or on processed products, except as otherwise provided in § 205.606;

(e) Excluded methods, except for vaccines: *Provided,* That, the vaccines are approved in accordance with § 205.600(a);

(f) Ionizing radiation, as described in Food and Drug Administration regulation, 21 CFR 179.26; and

(g) Sewage sludge.

§§ 205.106–205.199 [Reserved]

Subpart C—Organic Production and Handling Requirements

§ 205.200 General.

The producer or handler of a production or handling operation intending to sell, label, or represent agricultural products as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients or food group(s))'' must comply with the applicable provisions of this subpart. Production practices implemented in accordance with this subpart must maintain or improve the natural resources of the operation, including soil and water quality.

§ 205.201 Organic production and handling system plan.

(a) The producer or handler of a production or handling operation, except as exempt or excluded under § 205.101, intending to sell, label, or represent agricultural products as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients or food group(s))'' must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic system plan must meet the requirements set forth in this section for organic production or handling. An organic production or handling system plan must include:

(1) A description of practices and procedures to be performed and maintained, including the frequency with which they will be performed;

(2) A list of each substance to be used as a production or handling input, indicating its composition, source, location(s) where it will be used, and documentation of commercial availability, as applicable;

(3) A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented;

(4) A description of the recordkeeping system implemented to comply with the requirements established in § 205.103;

(5) A description of the management practices and physical barriers established to prevent commingling of organic and nonorganic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances; and

(6) Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.

(b) A producer may substitute a plan prepared to meet the requirements of another Federal, State, or local government regulatory program for the organic system plan: *Provided,* That, the submitted plan meets all the requirements of this subpart.

§ 205.202 Land requirements.

Any field or farm parcel from which harvested crops are intended to be sold, labeled, or represented as ''organic,'' must:

(a) Have been managed in accordance with the provisions of §§ 205.203 through 205.206;

(b) Have had no prohibited substances, as listed in § 205.105, applied to it for a period of 3 years immediately preceding harvest of the crop; and

(c) Have distinct, defined boundaries and buffer zones such as runoff diversions to prevent the unintended application of a prohibited substance to the crop or contact with a prohibited substance applied to adjoining land that is not under organic management.

§ 205.203 Soil fertility and crop nutrient management practice standard.

(a) The producer must select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion.

(b) The producer must manage crop nutrients and soil fertility through rotations, cover crops, and the application of plant and animal materials.

(c) The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. Animal and plant materials include:

(1) Raw animal manure, which must be composted unless it is:

(i) Applied to land used for a crop not intended for human consumption;

(ii) Incorporated into the soil not less than 120 days prior to the harvest of a product whose edible portion has direct contact with the soil surface or soil particles; or

(iii) Incorporated into the soil not less than 90 days prior to the harvest of a product whose edible portion does not have direct contact with the soil surface or soil particles;

(2) Composted plant and animal materials produced though a process that:

(i) Established an initial C:N ratio of between 25:1 and 40:1; and

(ii) Maintained a temperature of between 131° F and 170° F for 3 days using an in-vessel or static aerated pile system; or

(iii) Maintained a temperature of between 131° F and 170° F for 15 days using a windrow composting system, during which period, the materials must be turned a minimum of five times.

(3) Uncomposted plant materials.

(d) A producer may manage crop nutrients and soil fertility to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances by applying:

(1) A crop nutrient or soil amendment included on the National List of synthetic substances allowed for use in organic crop production;

(2) A mined substance of low solubility;

(3) A mined substance of high solubility: *Provided,* That, the substance is used in compliance with the conditions established on the National List of nonsynthetic materials prohibited for crop production;

(4) Ash obtained from the burning of a plant or animal material, except as prohibited in paragraph (e) of this section: *Provided,* That, the material burned has not been treated or combined with a prohibited substance or the ash is not included on the National List of nonsynthetic substances prohibited for use in organic crop production; and

(5) A plant or animal material that has been chemically altered by a manufacturing process: *Provided,* That, the material is included on the National

List of synthetic substances allowed for use in organic crop production established in § 205.601.

(e) The producer must not use:

(1) Any fertilizer or composted plant and animal material that contains a synthetic substance not included on the National List of synthetic substances allowed for use in organic crop production;

(2) Sewage sludge (biosolids) as defined in 40 CFR part 503; and (3) Burning as a means of disposal for crop residues produced on the operation: *Except,* That, burning may be used to suppress the spread of disease or to stimulate seed germination.

§ 205.204 Seeds and planting stock practice standard.

(a) The producer must use organically grown seeds, annual seedlings, and planting stock: *Except,* That,

(1) Nonorganically produced, untreated seeds and planting stock may be used to produce an organic crop when an equivalent organically produced variety is not commercially available: *Except,* That, organically produced seed must be used for the production of edible sprouts;

(2) Nonorganically produced seeds and planting stock that have been treated with a substance included on the National List of synthetic substances allowed for use in organic crop production may be used to produce an organic crop when an equivalent organically produced or untreated variety is not commercially available;

(3) Nonorganically produced annual seedlings may be used to produce an organic crop when a temporary variance has been granted in accordance with § 205.290(a)(2);

(4) Nonorganically produced planting stock to be used to produce a perennial crop may be sold, labeled, or represented as organically produced only after the planting stock has been maintained under a system of organic management for a period of no less than 1 year; and

(5) Seeds, annual seedlings, and planting stock treated with prohibited substances may be used to produce an organic crop when the application of the materials is a requirement of Federal or State phytosanitary regulations.

(b) [Reserved]

§ 205.205 Crop rotation practice standard.

The producer must implement a crop rotation including but not limited to sod, cover crops, green manure crops, and catch crops that provide the following functions that are applicable to the operation:

(a) Maintain or improve soil organic matter content;

(b) Provide for pest management in annual and perennial crops;

(c) Manage deficient or excess plant nutrients; and

(d) Provide erosion control.

§ 205.206 Crop pest, weed, and disease management practice standard.

(a) The producer must use management practices to prevent crop pests, weeds, and diseases including but not limited to:

(1) Crop rotation and soil and crop nutrient management practices, as provided for in §§ 205.203 and 205.205;

(2) Sanitation measures to remove disease vectors, weed seeds, and habitat for pest organisms; and

(3) Cultural practices that enhance crop health, including selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevalent pests, weeds, and diseases.

(b) Pest problems may be controlled through mechanical or physical methods including but not limited to:

(1) Augmentation or introduction of predators or parasites of the pest species;

(2) Development of habitat for natural enemies of pests;

(3) Nonsynthetic controls such as lures, traps, and repellents.

(c) Weed problems may be controlled through:

(1) Mulching with fully biodegradable materials;

(2) Mowing;

(3) Livestock grazing;

(4) Hand weeding and mechanical cultivation;

(5) Flame, heat, or electrical means; or

(6) Plastic or other synthetic mulches: *Provided,* That, they are removed from the field at the end of the growing or harvest season.

(d) Disease problems may be controlled through:

(1) Management practices which suppress the spread of disease organisms; or

(2) Application of nonsynthetic biological, botanical, or mineral inputs.

(e) When the practices provided for in paragraphs (a) through (d) of this section are insufficient to prevent or control crop pests, weeds, and diseases, a biological or botanical substance or a substance included on the National List of synthetic substances allowed for use in organic crop production may be applied to prevent, suppress, or control pests, weeds, or diseases: *Provided,* That, the conditions for using the substance are documented in the organic system plan.

(f) The producer must not use lumber treated with arsenate or other prohibited materials for new installations or replacement purposes in contact with soil or livestock.

§ 205.207 Wild-crop harvesting practice standard.

(a) A wild crop that is intended to be sold, labeled, or represented as organic must be harvested from a designated area that has had no prohibited substance, as set forth in § 205.105, applied to it for a period of 3 years immediately preceding the harvest of the wild crop.

(b) A wild crop must be harvested in a manner that ensures that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop.

§§ 205.208—205.235 [Reserved]

§ 205.236 Origin of livestock.

(a) Livestock products that are to be sold, labeled, or represented as organic must be from livestock under continuous organic management from the last third of gestation or hatching: *Except,* That:

(1) *Poultry.* Poultry or edible poultry products must be from poultry that has been under continuous organic management beginning no later than the second day of life;

(2) *Dairy animals.* Milk or milk products must be from animals that have been under continuous organic management beginning no later than 1 year prior to the production of the milk or milk products that are to be sold, labeled, or represented as organic: *Except,* That, when an entire, distinct herd is converted to organic production, the producer may:

(i) For the first 9 months of the year, provide a minimum of 80-percent feed that is either organic or raised from land included in the organic system plan and managed in compliance with organic crop requirements; and

(ii) Provide feed in compliance with § 205.237 for the final 3 months.

(iii) Once an entire, distinct herd has been converted to organic production, all dairy animals shall be under organic management from the last third of gestation.

(3) *Breeder stock.* Livestock used as breeder stock may be brought from a nonorganic operation onto an organic operation at any time: *Provided,* That, if such livestock are gestating and the offspring are to be raised as organic livestock, the breeder stock must be brought onto the facility no later than the last third of gestation.

(b) The following are prohibited:

(1) Livestock or edible livestock products that are removed from an

organic operation and subsequently managed on a nonorganic operation may be not sold, labeled, or represented as organically produced.

(2) Breeder or dairy stock that has not been under continuous organic management since the last third of gestation may not be sold, labeled, or represented as organic slaughter stock.

(c) The producer of an organic livestock operation must maintain records sufficient to preserve the identity of all organically managed animals and edible and nonedible animal products produced on the operation.

§ 205.237 Livestock feed.

(a) The producer of an organic livestock operation must provide livestock with a total feed ration composed of agricultural products, including pasture and forage, that are organically produced and, if applicable, organically handled: *Except,* That, nonsynthetic substances and synthetic substances allowed under § 205.603 may be used as feed additives and supplements.

(b) The producer of an organic operation must not:

(1) Use animal drugs, including hormones, to promote growth;

(2) Provide feed supplements or additives in amounts above those needed for adequate nutrition and health maintenance for the species at its specific stage of life;

(3) Feed plastic pellets for roughage;

(4) Feed formulas containing urea or manure;

(5) Feed mammalian or poultry slaughter by-products to mammals or poultry; or

(6) Use feed, feed additives, and feed supplements in violation of the Federal Food, Drug, and Cosmetic Act.

§ 205.238 Livestock health care practice standard.

(a) The producer must establish and maintain preventive livestock health care practices, including:

(1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;

(2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants);

(3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;

(4) Provision of conditions which allow for exercise, freedom of movement, and reduction of stress appropriate to the species;

(5) Performance of physical alterations as needed to promote the animal's welfare and in a manner that minimizes pain and stress; and

(6) Administration of vaccines and other veterinary biologics.

(b) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: *Provided,* That, such medications are allowed under § 205.603. Parasiticides allowed under § 205.603 may be used on:

(1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and

(2) Dairy stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.

(c) The producer of an organic livestock operation must not:

(1) Sell, label, or represent as organic any animal or edible product derived from any animal treated with antibiotics, any substance that contains a synthetic substance not allowed under § 205.603, or any substance that contains a nonsynthetic substance prohibited in § 205.604.

(2) Administer any animal drug, other than vaccinations, in the absence of illness;

(3) Administer hormones for growth promotion;

(4) Administer synthetic parasiticides on a routine basis;

(5) Administer synthetic parasiticides to slaughter stock;

(6) Administer animal drugs in violation of the Federal Food, Drug, and Cosmetic Act; or

(7) Withhold medical treatment from a sick animal in an effort to preserve its organic status. All appropriate medications must be used to restore an animal to health when methods acceptable to organic production fail. Livestock treated with a prohibited substance must be clearly identified and shall not be sold, labeled, or represented as organically produced.

§ 205.239 Livestock living conditions.

(a) The producer of an organic livestock operation must establish and maintain livestock living conditions which accommodate the health and natural behavior of animals, including:

(1) Access to the outdoors, shade, shelter, exercise areas, fresh air, and direct sunlight suitable to the species, its stage of production, the climate, and the environment;

(2) Access to pasture for ruminants;

(3) Appropriate clean, dry bedding. If the bedding is typically consumed by the animal species, it must comply with the feed requirements of § 205.237;

(4) Shelter designed to allow for:

(i) Natural maintenance, comfort behaviors, and opportunity to exercise;

(ii) Temperature level, ventilation, and air circulation suitable to the species; and

(iii) Reduction of potential for livestock injury;

(b) The producer of an organic livestock operation may provide temporary confinement for an animal because of:

(1) Inclement weather;

(2) The animal's stage of production;

(3) Conditions under which the health, safety, or well being of the animal could be jeopardized; or

(4) Risk to soil or water quality.

(c) The producer of an organic livestock operation must manage manure in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, heavy metals, or pathogenic organisms and optimizes recycling of nutrients.

§§ 205.240—205.269 [Reserved]

§ 205.270 Organic handling requirements.

(a) Mechanical or biological methods, including but not limited to cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, distilling, extracting, slaughtering, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing, and the packaging, canning, jarring, or otherwise enclosing food in a container may be used to process an organically produced agricultural product for the purpose of retarding spoilage or otherwise preparing the agricultural product for market.

(b) Nonagricultural substances allowed under § 205.605 and nonorganically produced agricultural products allowed under § 205.606 may be used:

(1) In or on a processed agricultural product intended to be sold, labeled, or represented as ''organic,'' pursuant to § 205.301(b), if not commercially available in organic form.

(2) In or on a processed agricultural product intended to be sold, labeled, or represented as ''made with organic (specified ingredients or food group(s)),'' pursuant to § 205.301(c).

(c) The handler of an organic handling operation must not use in or on agricultural products intended to be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made

with organic (specified ingredients or food group(s)),'' or in or on any ingredients labeled as organic:

(1) Practices prohibited under paragraphs (e) and (f) of § 205.105.

(2) A volatile synthetic solvent or other synthetic processing aid not allowed under § 205.605: *Except,* That, nonorganic ingredients in products labeled ''made with organic (specified ingredients or food group(s))'' are not subject to this requirement.

§ 205.271 Facility pest management practice standard.

(a) The producer or handler of an organic facility must use management practices to prevent pests, including but not limited to:

(1) Removal of pest habitat, food sources, and breeding areas;

(2) Prevention of access to handling facilities; and

(3) Management of environmental factors, such as temperature, light, humidity, atmosphere, and air circulation, to prevent pest reproduction.

(b) Pests may be controlled through:

(1) Mechanical or physical controls including but not limited to traps, light, or sound; or

(2) Lures and repellents using nonsynthetic or synthetic substances consistent with the National List.

(c) If the practices provided for in paragraphs (a) and (b) of this section are not effective to prevent or control pests, a nonsynthetic or synthetic substance consistent with the National List may be applied.

(d) If the practices provided for in paragraphs (a), (b), and (c) of this section are not effective to prevent or control facility pests, a synthetic substance not on the National List may be applied: *Provided,* That, the handler and certifying agent agree on the substance, method of application, and measures to be taken to prevent contact of the organically produced products or ingredients with the substance used.

(e) The handler of an organic handling operation who applies a nonsynthetic or synthetic substance to prevent or control pests must update the operation's organic handling plan to reflect the use of such substances and methods of application. The updated organic plan must include a list of all measures taken to prevent contact of the organically produced products or ingredients with the substance used.

(f) Notwithstanding the practices provided for in paragraphs (a), (b), (c), and (d) of this section, a handler may otherwise use substances to prevent or control pests as required by Federal, State, or local laws and regulations: *Provided,* That, measures are taken to prevent contact of the organically produced products or ingredients with the substance used.

§ 205.272 Commingling and contact with prohibited substance prevention practice standard.

(a) The handler of an organic handling operation must implement measures necessary to prevent the commingling of organic and nonorganic products and protect organic products from contact with prohibited substances.

(b) The following are prohibited for use in the handling of any organically produced agricultural product or ingredient labeled in accordance with subpart D of this part:

(1) Packaging materials, and storage containers, or bins that contain a synthetic fungicide, preservative, or fumigant;

(2) The use or reuse of any bag or container that has been in contact with any substance in such a manner as to compromise the organic integrity of any organically produced product or ingredient placed in those containers, unless such reusable bag or container has been thoroughly cleaned and poses no risk of contact of the organically produced product or ingredient with the substance used.

§§ 205.273—205.289 [Reserved]

§ 205.290 Temporary variances.

(a) Temporary variances from the requirements in §§ 205.203 through 205.207, 205.236 through 205.239, and 205.270 through 205.272 may be established by the Administrator for the following reasons:

(1) Natural disasters declared by the Secretary;

(2) Damage caused by drought, wind, flood, excessive moisture, hail, tornado, earthquake, fire, or other business interruption; and

(3) Practices used for the purpose of conducting research or trials of techniques, varieties, or ingredients used in organic production or handling.

(b) A State organic program's governing State official or certifying agent may recommend in writing to the Administrator that a temporary variance from a standard set forth in subpart C of this part for organic production or handling operations be established: *Provided,* That, such variance is based on one or more of the reasons listed in paragraph (a) of this section.

(c) The Administrator will provide written notification to certifying agents upon establishment of a temporary variance applicable to the certifying agent's certified production or handling operations and specify the period of time it shall remain in effect, subject to extension as the Administrator deems necessary.

(d) A certifying agent, upon notification from the Administrator of the establishment of a temporary variance, must notify each production or handling operation it certifies to which the temporary variance applies.

(e) Temporary variances will not be granted for any practice, material, or procedure prohibited under § 205.105.

§§ 205.291–205.299 [Reserved]

Subpart D—Labels, Labeling, and Market Information

§ 205.300 Use of the term, ''organic.''

(a) The term, ''organic,'' may only be used on labels and in labeling of raw or processed agricultural products, including ingredients, that have been produced and handled in accordance with the regulations in this part. The term, ''organic,'' may not be used in a product name to modify a nonorganic ingredient in the product.

(b) Products for export, produced and certified to foreign national organic standards or foreign contract buyer requirements, may be labeled in accordance with the organic labeling requirements of the receiving country or contract buyer: *Provided,* That, the shipping containers and shipping documents meet the labeling requirements specified in § 205.307(c).

(c) Products produced in a foreign country and exported for sale in the United States must be certified pursuant to subpart E of this part and labeled pursuant to this subpart D.

(d) Livestock feeds produced in accordance with the requirements of this part must be labeled in accordance with the requirements of § 205.306.

§ 205.301 Product composition.

(a) *Products sold, labeled, or represented as ''100 percent organic.''* A raw or processed agricultural product sold, labeled, or represented as ''100 percent organic'' must contain (by weight or fluid volume, excluding water and salt) 100 percent organically produced ingredients. If labeled as organically produced, such product must be labeled pursuant to § 205.303.

(b) *Products sold, labeled, or represented as ''organic.''* A raw or processed agricultural product sold, labeled, or represented as ''organic'' must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural products. Any remaining product ingredients must be organically produced, unless not commercially